

1 FEDERAL TRADE COMMISSION

2 I N D E X (PUBLIC RECORD)

3

4 WITNESS: DIRECT CROSS REDIRECT RECROSS

5 Bresnahan 1262 1269 (US)

6 1281 (SP)

7 Levy 1286

8

9 EXHIBITS FOR ID IN EVID

10 Joint

11 Number 3 1284*

12 Commission

13 None

14 Schering

15 None

16 Upsher

17 None

18

19 OTHER EXHIBITS REFERENCED PAGE

20 Commission

21 CX 13 1275

22 CX 18 1277

23 CX 133 1272

24 CX 341 1268

25 CX 347 1374

For The Record, Inc.
Waldorf, Maryland
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1	Commission	
2	CX 576	1315
3	CX 714	1372
4	CX 751	1263
5	CX 1042	1371
6	CX 1043	1372
7	CX 1044	1373
8	CX 1386	1374
9	CX 1597	1307
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12	CX 1601	1328
13	CX 1602	1320
14	CX 1603	1330
15	CX 1606	1342
16	CX 1607	1367
17	CX 1610	1380
18	Schering	
19	None	
20	Upsher	
21	USX 1005	1261
22		
23	*All exhibits referenced in Joint Exhibit 3 (attached)	
24	were admitted into evidence	
25		

For The Record, Inc.
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FEDERAL TRADE COMMISSION

In the Matter of:)
SCHERING-PLOUGH CORPORATION,)
a corporation,)
and)
UPSHER-SMITH LABORATORIES,) File No. D09297
a corporation,)
and)
AMERICAN HOME PRODUCTS,)
a corporation.)
-----)

Thursday, January 31, 2002

9:30 a.m.

TRIAL VOLUME 7

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Susanne Bergling, RMR

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1 P R O C E E D I N G S

2 - - - - -

3 JUDGE CHAPPELL: Back on the record, docket
4 9297.

5 Professor, I remind you you're still under
6 oath.

7 THE WITNESS: Yes, thank you.

8 JUDGE CHAPPELL: Mr. Kades, do you have further
9 redirect?

10 MR. KADES: Yes, I do, Your Honor.

11 JUDGE CHAPPELL: You may proceed.

12 MR. KADES: Thank you, Your Honor.

13 Whereupon--

14 TIMOTHY F. BRESNAHAN

15 a witness, called for examination, having previously
16 been duly sworn, was examined and testified further as
17 follows:

18 MR. KADES: Your Honor, before I begin, there
19 is one housekeeping matter. During Mr. Gidley's cross
20 examination, he used a document USX 1005. At the time
21 I objected on behalf of complaint counsel, because
22 based on the copy of the document we had, it wasn't
23 clear whether we had ever received the document.

24 Mr. Gidley has provided me a Bates numbered
25 copy of that document. So, we would withdraw that

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1 objection for the record.

2 JUDGE CHAPPELL: Okay, thank you, Mr. Kades.

3 MR. KADES: I wasn't sure if you had overruled
4 it or if the objection remained pending, so I just
5 wanted the record to be clear.

6 JUDGE CHAPPELL: I had overruled it to the
7 extent I had allowed him to inquire as to the
8 Professor's knowledge. I think that's the way he
9 proceeded with questioning. So, it wasn't substantive
10 evidence anyway, but thanks for letting me know.

11 REDIRECT EXAMINATION

12 BY MR. KADES:

13 Q. Good morning, Professor Bresnahan.

14 A. Good morning, Mr. Kades.

15 Q. I'd like to start with a mistake that's been
16 brought to my attention. Apparently during my direct
17 examination of you, at least at one point, I referred
18 to your opinion as being that the payment from Schering
19 to Upsher was not for delay. Is that your opinion?

20 A. No, my opinion is that it was for delay.

21 Q. Professor Bresnahan, the first thing I'd like
22 to talk to you about is a formula Mr. Nields and you
23 discussed towards the end of the day yesterday. Do you
24 remember that discussion?

25 A. I do.

1 Q. And if we could have CX 751, I believe it's
2 page 46.

3 Professor, was this the formula you were
4 discussing with Mr. Nields yesterday?

5 A. Yes.

6 Q. Professor Bresnahan, how does this formula
7 relate to your opinion that the payment from Schering
8 to Upsher was for delay?

9 A. This formula assumes that the payment was for
10 delay. It isn't one of the bases that -- under my
11 opinion that the payment was for delay.

12 Q. And the probability determination that you
13 made, what is that probability?

14 A. That's -- that's an inference based on payment
15 for delay plus some other assumptions, an inference
16 about Schering's subjective probability that it would
17 win the lawsuit.

18 Q. Now, Professor, the next topic I'd like to talk
19 to you about is -- relates to the market test that you
20 did. Do you remember talking about this test with Mr.
21 Gidley I guess it's probably two days ago now?

22 A. Yes.

23 Q. And during his questioning, you discussed
24 one -- a company in particular, Pierre Fabre?

25 A. I do remember that.

1 Q. And you discussed how many countries Pierre
2 Fabre was interested in in licensing the product from
3 Upsher?

4 A. Yes.

5 Q. And I'd like to show you the actual transcript
6 and then ask you about what you said. This is the
7 transcript of these proceedings dated January 29th, the
8 year 2000. The testimony begins on what's marked page
9 1054.

10 Do you see the testimony that begins at line 5,
11 the transcription that begins at line 5, Mr. Gidley
12 asks you:

13 "QUESTION: You testified earlier that Ms.
14 Vicki O'Neill testified under oath in her deposition
15 that Pierre Fabre was only operating in three
16 countries, did you not?"

17 And you answered, "No, no, no, that she -- that
18 she had mentioned the possibility of noncontingent
19 payments for three countries."

20 Then Mr. Gidley asked you, "Isn't it the case
21 that she talked about noncontingent payments being made
22 in as many as nine countries, sir?"

23 "ANSWER: I don't recall that."

24 Then the questioning continues on the next page
25 beginning at line 7. Mr. Gidley said to you:

1 "QUESTION: Sir, directing your attention to
2 the deposition of Ms. Vicki O'Neill, at transcript
3 pages 69 to 70," and then he proceeded to read this
4 testimony from Ms. O'Neill.

5 "QUESTION: Which countries would Pierre Fabre
6 have the ability to market Niacor-SR?

7 "ANSWER: I don't know if I'm qualified to say
8 what countries they had the ability to market
9 Niacor-SR. I could recall from their presentation what
10 companies they were currently marketing products in.

11 "QUESTION: What countries were they currently
12 marketing products? That is in June 1997.

13 "ANSWER: June of 1997, I believe in my recall
14 of that presentation there was approximately nine
15 countries where they were marketing product. These
16 countries included Spain, France, Greece, Germany,
17 Japan actually. A total of nine, which would be the
18 best place to see what their presentation had. But I
19 remember there being nine countries. I think they were
20 also in Mexico."

21 Do you remember Mr. Gidley reading you that
22 testimony?

23 A. I do.

24 Q. Now, Professor Bresnahan, why in your answer
25 did you say that it was three countries that were being

1 discussed for -- in terms of noncontingent payments?

2 A. Elsewhere, that's what Ms. O'Neill had said in
3 her deposition when she was talking about noncontingent
4 payments.

5 Q. Was it her deposition or her investigational
6 hearing?

7 A. I don't know.

8 Q. Could we have the O'Neill investigational
9 hearing?

10 For the record, this is the investigational
11 hearing of Ms. Vicki O'Neill taken August 30th in the
12 year 2000.

13 JUDGE CHAPPELL: What's her position or title?

14 BY MR. KADES:

15 Q. Professor Bresnahan, what is Ms. O'Neill's
16 title?

17 A. I'm not sure of her title. She works in the
18 corporate development function at Upsher and was
19 responsible for the marketing effort of these licenses
20 that they were doing in early 1997.

21 Q. And if we could have the excerpt.

22 Professor Bresnahan, is this the testimony you
23 were referring to?

24 A. Yes.

25 Q. What does that testimony say?

1 A. Ms. O'Neill was asked, "How many countries were
2 you talking about with Pierre Fabre?"

3 And answered, "You know, I really don't recall,
4 but I believe it was more than one, and I would have to
5 go back to see where they currently sell and market
6 products. I would say it was probably more like three.
7 And I can give you the context, and it's relative.
8 Pierre Fabre and Servier were more Pan-European. I
9 don't recall the number of countries that they were.
10 When we talked with Laboratories Esteve and Lacer, they
11 were Spain and Portugal. So, in our hierarchy of
12 interest, from Upsher-Smith's point of view, we were
13 more interested in Pierre Fabre and Servier, because
14 they represented more European countries."

15 Q. Professor Bresnahan, I'd now like to turn to
16 the discussion of direct evidence that Mr. Nields began
17 his examination of you with yesterday. Do you remember
18 that discussion?

19 A. I do.

20 Q. And do you remember when Mr. Nields reviewed
21 with you testimony from Schering-Plough employees taken
22 during the FTC's investigation that Schering -- that
23 the Schering employees refused to pay for delay?

24 A. Yes.

25 Q. And I'm going to show you a document created

1 not during the time of the investigation but at the
2 time of the Upsher settlement, CX 341, which is the
3 board of directors presentation. I believe the Bates
4 numbered page is 248.

5 I'm going to read you the blown-up portion. It
6 says, "Payment Terms: In the course of our discussions
7 with Upsher-Smith they indicated that a prerequisite of
8 any deal would be to provide them with a guaranteed
9 income stream for the next twenty-four months to make
10 up for the income that they had projected to earn from
11 sales of Klor Con had they been successful in their
12 suit. The guaranteed payments are as follows:

13 "Within 48 hours of Board Approval, \$28
14 million; First Anniversary of Board Approval, \$20
15 million; Second Anniversary of Board Approval, \$12
16 million."

17 Now, Professor, in forming your opinion that
18 the payment from Schering to Upsher was for delay, did
19 you consider both this statement and the statements
20 that Mr. O'Neill -- I'm sorry, that Mr. Nields talked
21 with you about yesterday?

22 A. Yes, I did.

23 Q. How did you reconcile that body of evidence?

24 A. This decisional document is from after those
25 statements were made in the negotiations. It's from

1 after the time the Schering people told the Upsher
2 people we can't pay you. But here, Schering is -- is
3 saying that it's a prerequisite of a deal with Upsher
4 to pay Upsher this uncontingent money, which is, in
5 fact, the amount of money that Upsher had been asking
6 for in the -- in the negotiations. So, I -- I credited
7 the -- this document more than the statements that we
8 told them we couldn't pay them.

9 MR. KADES: Your Honor, I have no further
10 questions.

11 JUDGE CHAPPELL: Thank you.

12 MR. GIDLEY: Your Honor, I have brief recross,
13 very brief.

14 JUDGE CHAPPELL: You may proceed.

15 RECROSS EXAMINATION

16 BY MR. GIDLEY:

17 Q. Good morning, Professor Bresnahan.

18 A. Good morning, Mr. Gidley.

19 Q. Let's start with the redirect we just heard on
20 the marketing effort and Ms. Vicki O'Neill. Now, the
21 marketing effort that Upsher-Smith was conducting in
22 1997 was just for Europe, was it not, sir?

23 A. That's my understanding, yes.

24 Q. And the license that Schering-Plough purchased
25 in the June 17, 1997 agreement was broader than that,

1 wasn't it, sir?

2 A. It was all non-NAFTA countries, yes.

3 Q. So, it included countries beyond Europe as well
4 as Europe, did it not, sir?

5 A. Yes, that's right.

6 Q. The deposition -- strike that. Excuse me, let
7 me clarify this.

8 This morning, Mr. Kades read to you from Ms.
9 O'Neill's investigational hearing transcript, did he
10 not?

11 A. Yes.

12 Q. The passage you and I discussed in cross
13 examination was from her subsequent deposition, was it
14 not?

15 A. I don't know. If -- if you say so, yes.

16 Q. Let me direct your attention to a second topic.
17 That's this business about product market.

18 Professor Bresnahan, on redirect, Mr. Kades
19 asked you questions about the relevant product market.
20 Do you recall that yesterday?

21 A. I do.

22 Q. In 1997, as now, K-Dur 20 was prescribed for
23 the purpose of treating potassium deficiency, was it
24 not, sir?

25 A. Yes.

1 Q. And in 1997, as now, Klor Con 8 and 10 were
2 prescribed for the purpose of treating potassium
3 deficiency, was it not?

4 A. That's right.

5 Q. And in 1997, as now, Micro-K is prescribed for
6 the purpose of treating potassium deficiency, is it
7 not?

8 A. Yes.

9 Q. And similarly in 1997, K-Tab was prescribed for
10 the purpose of treating potassium deficiency, was it
11 not?

12 A. Yes.

13 Q. And similarly, Slow K, K-Lyte, Klotrix,
14 Apothecon, potassium chloride 10 mEq and Ethex
15 potassium chloride were also prescribed for the purpose
16 of treating potassium deficiency, were they not?

17 A. Yes, I think so.

18 Q. And sir, sitting here today, you have no basis,
19 based on a patient's demographic background, that is,
20 age, sex, race, to identify any subclass of patients
21 for whom K-Dur 20 was the only appropriate potassium
22 treatment, do you, sir?

23 A. No, not based on demographics or other
24 classification criteria.

25 Q. And sir, in your report, you do not cite any

1 pharmaceutical trade periodicals that treat K-Dur 20 as
2 a separate product market, do you, sir?

3 A. No, I don't think I cite any pharmaceutical
4 trade periodicals at all, particularly not ones that
5 say that.

6 Q. Sir, isn't it the case that K-Dur 10 and K-Dur
7 20 are manufactured in the same factory, are they not?

8 A. I believe they are.

9 Q. Let me direct your attention to a third topic,
10 and that's this issue of CX 133, and let me just put
11 that up on the ELMO. Let's see, I've got to turn it
12 on.

13 Professor Bresnahan, do you remember CX 133 and
14 being asked a series of questions yesterday afternoon?

15 A. I do.

16 Q. Now, late yesterday afternoon, you testified to
17 some calculations about 1997 hypothetical events based
18 on CX 133, did you not?

19 A. Yes.

20 Q. And the only pricing data that you were using
21 in that series of questions that Mr. Kades asked you
22 was coming from CX 133, correct?

23 A. Yes, that's right.

24 Q. And sir, as far as you know, this document
25 contains both K-Dur 10 and K-Dur 20 market share data,

1 does it not, in terms of prescriptions?

2 A. Yes.

3 Q. Now, you were asked yesterday to calculate
4 hypothetically an average price that blended the price
5 of K-Dur potassium chloride with generic potassium
6 chloride based on CX 133, right?

7 A. Yes.

8 Q. And that is hypothetical in the sense that it
9 didn't happen, because there was not generic entry, as
10 you defined it, in the year 1997. Isn't that correct?

11 A. That's right.

12 Q. And further, an average price is hypothetical
13 in any event as to any single consumer, because no
14 single patient actually gets an average prescription.
15 The patient either gets K-Dur 20 or the patient gets
16 something else. Isn't that the case?

17 A. That's right. I mean, the -- it could happen
18 that someone actually paid the average price, but
19 that's not the meaning of average price that any
20 individual literally would pay. It's the average of
21 the -- it's -- the idea is that it's an average of
22 the -- of the prices that were charged in the
23 marketplace, and, you know, in both the questions you
24 asked me and the questions Mr. Kades asked me.

25 Q. But again, the case remains that a single

1 patient does not get an average price; an individual
2 patient gets the actual price of the prescription that
3 is issued. Isn't that the case, sir?

4 A. Right, which would only coincidentally be the
5 average price.

6 Q. Now, let's turn to reality. After September 1,
7 2001, you have not reviewed systematic statistical
8 pricing data on the price for K-Dur 20. Isn't that the
9 case?

10 A. That's correct.

11 Q. And sir, sitting here today, you don't know if
12 the price of K-Dur 20 has dropped at all since
13 September 1, 2001. Isn't that the case?

14 A. That's correct.

15 Q. On this business of product market, in your
16 product market definition, K-Dur 10 is not in your
17 K-Dur 20 mEq product market as you define it, sir, is
18 it?

19 A. No, it's not.

20 Q. And sir, you haven't yourself addressed or
21 studied the question of whether K-Dur 10 and Klor Con
22 10 compete, have you?

23 A. No.

24 Q. This will be my second to last topic, just one
25 second.

1 Let me get you a book. I want to go back to
2 the cross examination exhibits to shed some light on
3 this K-Dur 10 versus K-Dur 20 question.

4 May I approach, Your Honor?

5 JUDGE CHAPPELL: Yes.

6 THE WITNESS: Thank you.

7 BY MR. GIDLEY:

8 Q. Professor Bresnahan, I'd like to direct your
9 attention to tab 1 of the blue book of exhibits. This
10 is CX 13. Do you see that, sir?

11 A. I do.

12 Q. And yellow highlighted at the bottom of the
13 page is the quote K-Dur 20 TRX market share is 29
14 percent. Do you see that?

15 A. I do.

16 Q. And that means as of the time of this document,
17 March of 1995, seven out of ten prescriptions for
18 potassium chloride were for something other than K-Dur
19 20. Is that not the case?

20 A. That's right.

21 Q. Directing your attention to tab 2, which is the
22 K-Dur marketing research backgrounder, sir.

23 A. Yes.

24 Q. CX 746. Let me direct your attention within
25 that document. Please go to page 24, Appendix A-3.

1 A. Yes, I've got it.

2 Q. I want to direct your attention to a number I
3 don't believe we focused on before that will shed a
4 little light on this 10 and 20 question. Professor,
5 whether you look at the screen or whether you look at
6 the document, I want to direct your attention to the
7 two lines K-Dur 10 and K-Dur 20 underneath the column
8 heading Year to Date April '96 TRX.

9 A. Yes.

10 Q. And I believe we established before that that
11 column relates to year to date April 1996 TRX, total
12 prescriptions, did we not?

13 A. Yes.

14 Q. And that's the way that Schering-Plough looked
15 at market share in the context of this document, did
16 they not?

17 A. That's correct.

18 Q. And directing your attention to K-Dur 10, the
19 number that appears is 5 percent of TRX or total
20 prescriptions year to date April '96. Isn't that the
21 case?

22 A. Yes.

23 Q. And similarly, K-Dur 20 is 32 percent of TRX
24 year to date April '96. Isn't that the case?

25 A. Yes.

1 Q. If you were to add those two numbers, 5 percent
2 market share points and 32 percent market share points,
3 that would yield a sum of 37 percent of TRX. Is that
4 not the case, sir?

5 A. Yes.

6 Q. Let me direct your attention, sir, to tab 3 and
7 the pie chart that's found there. Tab 3 is CX 18, the
8 1997 K-Dur marketing plan. Again, sir, directing your
9 attention to page 5 of CX 18, you see the pie slice
10 that we discussed earlier of K-Dur, 37 percent, do you
11 not?

12 A. I do.

13 Q. And it's year to date April 1996.

14 A. Yes.

15 Q. So, it includes K-Dur 10 and K-Dur 20, does it
16 not, sir?

17 A. Yes.

18 Q. So, the actual market share of K-Dur 20 would
19 actually be less than 37 percent as expressed in this
20 document. Is that not the case?

21 A. That's correct.

22 Q. And similarly, sir, directing your attention to
23 tab 4, which takes us back to CX 133?

24 A. Yes.

25 Q. And if I might, could I direct your attention

1 to the 1996 collection of column headings.

2 A. Yes.

3 Q. And sir, do you see the line that says "April
4 1996"?

5 A. Yes.

6 Q. Reading across into the column that says, "1996
7 K-D Market Share," do you see that?

8 A. I do.

9 Q. That figure is also 37 percent, is it not, sir?

10 A. Yes.

11 Q. That would appear to tie to the previous
12 document, would it not, sir?

13 A. Yes.

14 Q. And wouldn't it be a fair inference, sir, that
15 this includes both K-Dur 10 and K-Dur 20 sales, does it
16 not, sir?

17 A. Yes.

18 Q. And finally, sir, directing your attention to
19 tab 7, which is the 1998 K-Dur marketing plan dated
20 August 1, 1997, a Schering document?

21 A. Yes.

22 Q. Could I direct your attention to the pie chart
23 on that page.

24 A. Yes. I'm sorry, what page?

25 Q. Page 5.

1 A. Thank you.

2 Q. And again, sir, this pie chart is expressed in
3 TRX, is it not, sir?

4 A. It is.

5 Q. And it includes both K-Dur 10 and K-Dur 20,
6 does it not, sir?

7 A. Yes.

8 Q. So that the 38 percent market share figure that
9 Schering reports here combines K-Dur 10 and K-Dur 20,
10 does it not, sir?

11 A. Yes, in the sense they use "market share" here.

12 Q. Yes, sir. And as this document reflects, the
13 actual market share of K-Dur 20 would actually be
14 something less than 38 percent in the context of this
15 document, in the context of total prescriptions. Is
16 that not the case, sir?

17 A. Right, in the sense it uses "market share"
18 here, it would be less.

19 Q. So, at this point in time, sir, in total
20 prescriptions, more than six out of ten potassium
21 chloride prescriptions were for something other than
22 K-Dur 20. Is that not the case?

23 A. Yes.

24 Q. The final topic, sir.

25 Do you recall yesterday -- you can set those

1 materials down.

2 A. Thank you.

3 Q. Do you recall yesterday on redirect Mr. Kades
4 asking you a series of questions about the board
5 presentation and the market value contained therein
6 that was calculated in a spreadsheet for the Niacor-SR
7 license? Do you recall that?

8 A. I do.

9 Q. Sir, you've never been retained to value a
10 patent. Isn't that correct?

11 A. That's correct.

12 Q. And you don't maintain a database of
13 pharmaceutical patents and their history or valuation,
14 do you, sir?

15 A. I do not.

16 Q. Before this case, you had never performed a
17 valuation of a pharmaceutical product. Isn't that the
18 case?

19 A. That's correct.

20 Q. You've never testified before in a
21 pharmaceutical industry case, have you, sir?

22 A. No, I have not.

23 Q. And you've never been hired to value a
24 pharmaceutical in-licensing opportunity, have you, sir?

25 A. No, not in this case or before.

1 MR. GIDLEY: Pass the witness, Your Honor.

2 JUDGE CHAPPELL: Mr. Nields?

3 RECROSS EXAMINATION

4 BY MR. NIELDS:

5 Q. Professor, you recall John Hoffman's testimony,
6 don't you?

7 A. Yes.

8 Q. That any transaction that might be done with
9 Upsher to meet its desire for cash would have to stand
10 on its own two feet?

11 A. I recall him saying that.

12 Q. And isn't it the case that in the very document
13 that Mr. Kades just showed you a few moments ago, there
14 is that exact same idea set forth in writing?

15 A. The -- in writing, it says -- not in those
16 words -- we told Upsher that it had to -- not stand on
17 its own two feet, but on its own merit.

18 Q. "That any such deal should stand on its own
19 merit independent of the settlement." Those are the
20 words in the document Mr. Kades showed you, aren't
21 they?

22 A. Yes. That's not the complete sentence, but
23 those are the words.

24 MR. NIELDS: I have nothing further, Your
25 Honor.

1 JUDGE CHAPPELL: Professor, did you offer your
2 opinion on what the relevant product market is in this
3 case?

4 THE WITNESS: I did.

5 JUDGE CHAPPELL: Is that an opinion -- is that
6 an economic opinion or a legal opinion?

7 THE WITNESS: That's an economic opinion.

8 JUDGE CHAPPELL: And what did you rely on in
9 forming that opinion?

10 THE WITNESS: I relied on the economic
11 literature about pharmaceutical markets generally, on
12 the documents that were produced by the firms at the
13 time, particularly those forecast and projection
14 documents. I relied on the -- what happened after
15 September 1st, 2001 actually in the marketplace in
16 those early months of statistical data, and I relied on
17 how the managers in -- to some degree in their
18 testimony in the depositions, I guess IHs, too, and in
19 their documents explained those outcomes.

20 JUDGE CHAPPELL: Okay. Tell me again what your
21 opinion is of the relevant product market.

22 THE WITNESS: My opinion is that it's 20
23 milliequivalent tablets and capsules of potassium
24 chloride.

25 JUDGE CHAPPELL: And in forming that opinion,

1 did you rely on any other expert's opinions or the
2 opinions of other people, or is this just your opinion?

3 THE WITNESS: No, this is -- that doesn't rely
4 on the opinions of any other experts. I mean, it
5 relies in the sense I just said on the -- on what the
6 business people said and forecast.

7 JUDGE CHAPPELL: Thank you.

8 Any questions based on my questioning of the
9 witness?

10 MR. GIDLEY: No, Your Honor.

11 MR. NIELDS: No, Your Honor.

12 MR. KADES: No, Your Honor.

13 JUDGE CHAPPELL: Professor, you're excused.
14 Thank you.

15 THE WITNESS: Thank you, sir.

16 JUDGE CHAPPELL: Complaint counsel, call your
17 next witness.

18 MS. BOKAT: Your Honor, before we call the next
19 witness, may we offer a joint exhibit into evidence,
20 please, because the next witness is going to be relying
21 in part on some of the documents addressed here?

22 JUDGE CHAPPELL: Yes, you may.

23 Off the record.

24 (Discussion off the record.)

25 JUDGE CHAPPELL: Ms. Bokat, you had a joint

1 exhibit or a joint motion or what is it?

2 MS. BOKAT: Yes, Your Honor, this is a joint
3 stipulation of exhibits to be offered in evidence. It
4 has been marked JX-3. It is signed by counsel for all
5 three parties. It's an offer in evidence of a number
6 of Schering documents and -- excuse me, exhibits, SPXs
7 and a few CXs, complaint counsel exhibits.

8 JUDGE CHAPPELL: Do you have a copy?

9 MS. BOKAT: May I approach?

10 JUDGE CHAPPELL: Yes.

11 MS. BOKAT: I have the original for the court
12 reporter.

13 JUDGE CHAPPELL: And JX-3 is agreed to by the
14 respondents?

15 MS. SHORES: It is, Your Honor.

16 MR. CURRAN: Yes, Your Honor.

17 JUDGE CHAPPELL: JX-3 is admitted.

18 (JX Exhibit Number 3 was admitted into
19 evidence.)

20 MS. BOKAT: Thank you, Your Honor.

21 Complaint counsel call Dr. Nelson Levy.

22 JUDGE CHAPPELL: Raise your right hand, please.
23 Whereupon--

24 NELSON L. LEVY

25 a witness, called for examination, having been first

1 duly sworn, was examined and testified as follows:

2 JUDGE CHAPPELL: Thank you, be seated.

3 State your full name for the record, please.

4 THE WITNESS: Nelson Louis, L O U I S, Levy.

5 MR. SILBER: Good morning, Your Honor. I'm
6 Seth Silber for complaint counsel.

7 JUDGE CHAPPELL: Good morning.

8 MR. SILBER: If we could just have a couple
9 moments to set up.

10 JUDGE CHAPPELL: Okay.

11 (Pause in the proceedings.)

12 JUDGE CHAPPELL: You may proceed.

13 MR. SILBER: Before I begin, Your Honor --
14 actually, one of the people I wanted to introduce just
15 stepped out, but I would like to introduce two people
16 who have been integral in helping us prepare Dr. Levy's
17 work in this case and his testimony here today.

18 First I'd like to introduce Mr. Karan Singh,
19 he's an attorney who recently joined the Commission,
20 and Ms. Paula Katz, who is one of our honors
21 paralegals.

22 JUDGE CHAPPELL: Thank you. They learned they
23 need to stand up when you introduce them.

24 MR. SILBER: We learned that from the last
25 time, Your Honor.

1 DIRECT EXAMINATION

2 BY MR. SILBER:

3 Q. Good morning, Dr. Levy.

4 A. Good morning.

5 Q. Before we start working on your -- going
6 through your qualifications, could you describe for us
7 in general the issues the FTC requested that you
8 address?

9 A. Yes. I was asked to provide an opinion on
10 whether a certain \$60 million payment that was made by
11 Schering-Plough to Upsher-Smith pursuant to an
12 agreement in June of 1997 could reasonably have been
13 for a pharmaceutical product called Niacor-SR and a
14 small group of additional generic pharmaceuticals.

15 Q. Dr. Levy, have you come to Court today prepared
16 to testify as to whether the \$60 million noncontingent
17 payment was for Niacor-SR?

18 A. Yes, I have.

19 Q. Going to your qualifications, let's start, Dr.
20 Levy, with -- can you tell us what your present
21 business or profession is?

22 A. Yes, I am the chairman and chief executive
23 officer of a company called the CoreTechs Corporation.

24 Q. And have you prepared a slide that describes
25 how you got to your present career position?

1 A. Yes, I have.

2 Q. Okay. And Dr. Levy, what I've put on the ELMO,
3 is this the slide you're referring to?

4 A. Yes, it is.

5 Q. Okay. Let's start with your education. The
6 first thing you have listed is Yale University. What
7 degree did you receive from Yale?

8 A. I was graduated in 1963 with both a Bachelor of
9 Arts and a Bachelor of Science degree.

10 Q. Okay. Did you receive any distinctions while
11 you were at Yale?

12 A. Yes, I did.

13 Q. What were those distinctions?

14 A. I was graduated Summa Cum Laude, Junior Phi
15 Beta Kappa, and I was the Scholar of the House.

16 Q. Can you tell us what a Scholar of the House is?

17 A. Yes, at the end of one's junior year, the
18 faculty select nine individuals chosen from the --
19 across the academic spectrum, two from the sciences
20 typically, and those individuals are excused from all
21 classes and exams during their senior year, have no
22 requirements of the major and are then able to do
23 original research.

24 MR. SILBER: Your Honor, if I may, just for
25 identification purposes, this slide is marked as

1 CX 1598 and is titled Nelson L. Levy, M.D., Ph.D.

2 BY MR. SILBER:

3 Q. After receiving your degree from Yale, what did
4 you do next?

5 A. I went to Columbia University College of
6 Physicians and Surgeons in New York City.

7 Q. And that is where you received your M.D.
8 degree?

9 A. Yes, sir.

10 Q. Okay. And what did you do after receiving this
11 degree from Yale?

12 A. I didn't put it on this slide, but I went -- I
13 did an internship which was a combined internship done
14 half at the University of Colorado Medical Center in
15 Denver and half at the Massachusetts General Hospital
16 in Boston, the purpose of it being -- well, to pursue
17 an interest I had then in transplantation, and I was
18 fortunate to spend a six-month period in Denver under a
19 man named Tom Starzl, who at that time was and I
20 believe still is the world's leading transplantation
21 surgeon.

22 And during that year -- it was a very exciting
23 year, so I like to talk about it. It was a year
24 that -- Dr. Starzl is the man who did the first -- the
25 world's first liver transplant, and I was fortunate

1 enough to scrub on that case with him.

2 Q. After completing this training, the next item
3 is NIH. Did you then go to the NIH?

4 A. Yes, sir.

5 Q. Okay. And can you tell us what kind of work
6 you did at NIH?

7 A. Yes. I was what they refer to as a research
8 associate and spent the full two-year period that I was
9 there doing research in the areas of cancer --
10 cancer-oriented research but in the -- specifically in
11 the areas of virology and immunology.

12 Q. How many years did you spend at NIH?

13 A. Two years.

14 Q. Okay. And where did you conduct your
15 residency?

16 A. Well, I then went to Duke University Medical
17 Center after I left the NIH and wore several hats
18 there. One hat was -- I was a resident in
19 neurosurgery. The second hat was that I was a graduate
20 student in microbiology and immunology, and the third
21 hat was -- which was particularly bizarre -- is that I
22 was an -- I was actually an instructor on the faculty
23 of the same department in which I was getting my Ph.D.

24 Q. What types of students did you teach?

25 A. Medical students and graduate students.

1 Q. And did you conduct clinical research while you
2 were at Duke?

3 A. Yes, I did.

4 Q. What type of clinical research?

5 A. There were three areas. I ran two of the major
6 clinics. One was the melanoma clinic, melanoma being
7 one of the forms of skin cancer. The second was I ran
8 the multiple sclerosis clinic. And thirdly, a
9 particular focus of research in my laboratory were
10 brain tumors, specifically gliomas, and we did clinical
11 research as well as basic research in all three of
12 those areas.

13 Q. How many years in total did you spend at Duke?

14 A. Eleven.

15 Q. And what year was that that you finished your
16 work at Duke?

17 A. 1981.

18 Q. By the time you were finished with your work at
19 Duke, had you published articles in the medical field?

20 A. Yes, sir.

21 Q. How many articles in total?

22 A. A little over 130.

23 Q. Can you -- are any of those articles relevant
24 to your testimony here today?

25 A. That's an interesting question. I think

1 everything was relevant in that this case cuts across
2 multiple areas of study, and certainly a familiarity
3 with clinical research, a familiarity with medicine,
4 the familiarity with the questions of the efficacy or
5 lack thereof of pharmaceuticals is all embedded in this
6 case, and the full experience that I have as a
7 professor, designing research projects, conducting
8 research projects, assessing data and the like I think
9 is all germane to this case.

10 Q. When you left Duke after your 11 years there,
11 what position did you hold?

12 A. Professor -- well, tenured professor of
13 microbiology and immunology.

14 Q. And at that point, what degrees did you hold?

15 A. An M.D. degree and Ph.D. degree.

16 Q. What was your Ph.D. in?

17 A. Immunology.

18 Q. In 1981, you indicated that you left Duke.
19 What did you do next?

20 A. I went to Abbott Laboratories as the vice
21 president of pharmaceutical research.

22 Q. Okay. How many years did you spend at Abbott?

23 A. About three and a half.

24 Q. Okay. Now, you indicated you were the vice
25 president of pharmaceutical research. Can you describe

1 for us what your responsibilities were in that
2 position?

3 A. Yes, I had under my supervision all the
4 research that Abbott Laboratories, which is, of course,
5 one of the major health care and pharmaceutical
6 companies in the world, all the research that Abbott
7 did of any type dealing with any pharmaceutical
8 product.

9 Q. Based on your efforts at Abbott, did those
10 efforts lead to any marketed pharmaceuticals?

11 A. Yes, sir.

12 Q. Okay. Approximately how many?

13 A. About five or six what I would say major
14 pharmaceuticals, and then there was a multitude of
15 smaller things that we referred to as line extensions.

16 Q. Okay. I am going to introduce a term in my
17 next question, I'd like you to tell us what it means
18 first, because it's going to come up a lot if it hasn't
19 come up already. The term is "in-licensing."

20 A. Yes.

21 Q. Can you tell us what in-licensing is?

22 A. Licensing in.

23 Q. Can you elaborate a bit?

24 A. In-licensing is when a -- one party, referred
25 to as the licensee, acquires a product from a third

1 party, referred to as the licensor, and extends its
2 product line in so doing.

3 Q. Okay. Now, getting back to your relevant
4 qualifications, we had talked about you were involved
5 in pharmaceutical research at Abbott. While at Abbott,
6 did you have any involvement in issues concerning the
7 in-licensing of pharmaceutical products?

8 A. Yes, I did, I think in -- in two principal
9 ways. First, whenever any product was being considered
10 for in-licensing at Abbott, it would go -- before any
11 serious consideration was given to it, it would go
12 through the research and development departments, and
13 that was under my supervision, and so it had to come
14 across my desk, and then it was my responsibility to
15 see that it was handed off to the various -- the
16 various and sundry experts under my supervision.

17 Secondly, I sat on for the full time that I was
18 there what Abbott referred to as the Pharmaceutical
19 Business Development Committee, and this was comprised
20 of the vice president of business development -- I
21 think we actually called him vice president of
22 licensing, a man named Frank Barnes, the vice president
23 of marketing in the domestic pharmaceutical business at
24 that time was a guy named Dick McMahon, and the -- his
25 counterpart in the international division, a fellow

1 named Bob Pickholtz, myself, the -- the chief financial
2 officer from Abbott's international division, Dick
3 Williams, and Mark Barmak, who was at that time -- he's
4 now the general counsel of Abbott, I believe, but at
5 that time he was Abbott's in-house patent counsel or
6 head in-house patent counsel.

7 Q. Okay. During your three and a half years at
8 Abbott, could you approximate for us how many
9 pharmaceutical products you were involved in looking at
10 in some capacity as far as in-licensing?

11 A. Oh, gee, a few dozen. You know, most of them
12 were rejected, but your question I think was to how
13 many did we look at.

14 Q. Yes.

15 A. At least a few dozen.

16 Q. Now, you indicated you started at Abbott in
17 1981, you were there about three and a half years, that
18 brings us to about 1984. Is that correct?

19 A. Yes, sir.

20 Q. And what did you do in 1984?

21 A. I left Abbott to form the company CoreTechs.

22 Q. Okay. Describe for us what CoreTechs' business
23 is.

24 A. CoreTechs has two businesses, and the first
25 I'll mention has diminished progressively over the

1 years. The first is -- was consulting to the
2 pharmaceutical industry and to the investment community
3 servicing the biotech and pharmaceutical industries.
4 The second was a paradigm that we developed for what's
5 referred to as technology transfer, and technology
6 transfer is the identification and valuation of
7 technologies from universities, from large companies,
8 from small companies, and then taking these
9 technologies forward into some form of development,
10 either through licensing or through the formation of a
11 startup company.

12 Q. The first part of CoreTechs' business that you
13 described you were working on referred to consultant
14 business. Could you give us a few examples of relevant
15 experiences you've had at CoreTechs as a consultant
16 with the pharmaceutical industry?

17 A. Yes. I tried to list on this slide,
18 recognizing that it was for this proceeding, a few
19 examples, and I chose them for a few reasons. First,
20 to show the diversity of experiences. Secondly, each
21 of those three that I'll speak of in a moment I had a
22 very long-term relationship with as opposed to a -- you
23 know, a cursory consulting assignment. And -- well,
24 that's it.

25 Q. Okay. Let's just go to the first one that

1 you've listed. It's Erbamont Pharmaceutical Company.
2 Can you describe the work that you have done or that
3 you did do with Erbamont?

4 A. Yes. Erbamont was a pharmaceutical company
5 that was formed -- it was traded on the New York Stock
6 Exchange, and it did about \$2 and a half billion in
7 sales at the time, so it was a major company, and it
8 was comprised of three major divisions. One was Adria
9 Laboratories in this country, which sold the -- as its
10 principal product the drug called adriamycin, which at
11 that time was the world's leading selling anti-cancer
12 drug, adriamycin. Secondly, it had a small diagnostics
13 division called Kallestad headquartered in Austin,
14 Texas.

15 But most significant was the fact that by far
16 its largest division was a company called Farmitalia
17 Carlo Erba, which was Italy's largest pharmaceutical
18 company and was indeed the place where adriamycin was
19 discovered, and it was headquartered in Milan and had
20 roughly 1500 people in its R&D department, and I became
21 involved with Erbamont -- actually, the CEO of the
22 company had been a colleague at Abbott and wanted me to
23 go there as his worldwide head of R&D. I told him I
24 didn't want to do that, and so I agreed to work half
25 time as a consultant for him but with the

1 responsibility and authority actually to run his
2 worldwide research and development operations. So, I
3 was essentially functioning as the vice president of
4 Erbamont's worldwide R&D.

5 Q. During what years did you function in this
6 capacity for Erbamont?

7 A. I -- I continued to work with Erbamont from
8 1984 to -- it was about 1989 or so but intensely for
9 about almost two years during the period that I had
10 this role that I was speaking of before, and at that
11 time was going to Milan for usually about a week every
12 four to six or seven weeks.

13 Q. The next company listed there under CoreTechs
14 here is Ligand Pharmaceuticals. Tell us what you did
15 with Ligand.

16 A. Yes, Ligand is now a public company with almost
17 a billion dollar market cap. It's one of the more
18 successful among the -- let's just say the early stage
19 pharmaceutical companies. I've been involved with that
20 company since before it went public in the -- in the
21 eighties. It is probably the world's leading company
22 in the area -- in a particular area of pharmaceutical
23 research that deals with what are referred to as
24 intracellular receptors, and I have been -- first,
25 early on, I was on the board of directors, but very

1 briefly.

2 Since the eighties, I've been on Ligand's
3 Scientific Advisory Board and have been what they refer
4 to as a special counsel to the CEO. That's given me
5 the opportunity to be involved with a -- the multitude
6 of transactions that Ligand's been involved with over
7 the past more than decade. Ligand's been very active
8 in out-licensing a number of its research programs as
9 well as having made some major acquisitions itself that
10 have led to the, if you will, the in-licensing of some
11 significant pharmaceutical products, and I've been
12 involved with all of that.

13 Q. The last company listed here is
14 LyphoMed/Fujisawa. Tell us about your involvement with
15 that entity.

16 A. Yes, well, LyphoMed began -- I believe it began
17 in the early eighties as a very narrowly focused
18 generic pharmaceutical company. In 1984, John Kapoor,
19 who was the founder and CEO of that company, approached
20 me, because he had hired one of my former employees
21 from Abbott, and he just wanted me to become, you know,
22 a counselor to him with the idea of trying to take
23 LyphoMed from being a purely generic pharmaceutical
24 company to one that had branded pharmaceutical
25 products.

1 And so over the course of the next, oh, I guess
2 five years, I worked with LyphoMed to help them find,
3 evaluate and ultimately in-license five different
4 branded pharmaceutical products.

5 Q. At some point in time, did you become a
6 full-time employee of Fujisawa?

7 A. Well, I didn't mention that in I believe it was
8 1989 or 1990 -- I think it was late in 1989, Fujisawa,
9 which was the third largest pharmaceutical company in
10 Japan, bought LyphoMed for almost a billion dollars,
11 and so my interactions with LyphoMed now became --
12 continued and they became interactions with Fujisawa,
13 and then finally in 1992, they asked me to become the
14 president of Fujisawa, which I did.

15 Q. Okay, and you were president of Fujisawa's
16 North American entity. Is that correct?

17 A. Yes, sir.

18 Q. So, you headed up the entire North American
19 operations for this Japanese company?

20 A. Yes, Fujisawa had three major pharmaceutical
21 divisions. One was, of course, the domestic Japanese
22 company, which was -- sold in Japan and the Far East.
23 Then they had a subsidiary in Europe, which they had
24 acquired, had previously been Klinge Pharma, it was
25 headquartered in Munich, and then they had -- which

1 became Fujisawa GMBH, and then they had Fujisawa USA,
2 which was Fujisawa North America, and we had North
3 America or United States and Canada, and that was under
4 my supervision. We had roughly \$250 million in sales
5 and about 1500 employees.

6 Q. As the head of Fujisawa's North American
7 operation, can you relate to us how that experience is
8 relevant to your testimony today?

9 A. Yes. I think that -- and again, in a number of
10 fashions. Generally speaking, I had the opportunity to
11 head an entire significant pharmaceutical business and
12 so had under my supervision the in-licensing or
13 business development, as we called it, department, and,
14 of course, had all the other elements of a
15 pharmaceutical business in terms of marketing, sales,
16 finance and the like, all of which components have to
17 work together and interrelate to form a pharmaceutical
18 business.

19 Then I think more specifically, Fujisawa had a
20 major pharmaceutical under development in this country,
21 which has now been registered, it's a drug -- we called
22 it then FK-506, but it's now called Prograf, and it's
23 one of the major drugs in the world for
24 immunosuppression; that is, to fight the rejection of
25 transplants.

1 But also, because the business -- the North
2 American business was somewhat nascent, it was actively
3 involved in doing in-licensing deals or trying to find
4 them and also have the responsibility to out-license
5 some opportunities that were developed internally by
6 Fujisawa in Japan. So, we had the opportunity and the
7 responsibility to seek out-licensing partners for some
8 of Fujisawa Japan's opportunities in North America.

9 Q. Now, you started with Fujisawa in 1991 --

10 A. '92 -- well, I mean I became a full-time
11 employee in '92.

12 Q. Okay, thank you. Then at some point, did you
13 return to CoreTechs?

14 A. Yes, I did, in --

15 Q. In what year?

16 A. -- roughly mid-1993, I went back to CoreTechs,
17 had an interesting opportunity arise.

18 Q. And you're still with CoreTechs today?

19 A. Yes, I am.

20 Q. And what is your current title?

21 A. I'm now the chairman and the CEO.

22 Q. Okay. Can you tell us in your work at
23 CoreTechs since 1993 some examples of other
24 pharmaceutical companies you've worked with that are
25 relevant to your testimony here today?

1 A. Yes. Well, I mean first, the -- the
2 interactions with the three I listed above have
3 continued, although Erbamont doesn't exist anymore, it
4 has subsequently been acquired, so that -- that has
5 ceased, but the other two certainly do. And then I've
6 listed, again, just as illustrations of the sorts of
7 things that I've been involved with a few other
8 opportunities that I think are germane.

9 First is I have been and was for a little over
10 two years, almost three years actually, a member of the
11 board of directors of Zonagen. Zonagen is a publicly
12 traded company, and it's quite germane to this
13 proceeding in that Zonagen licensed its major
14 pharmaceutical product to Schering-Plough, and I'm, of
15 course, exceedingly familiar with that opportunity and
16 with the manner in which Schering-Plough has carried
17 out the business post having done that deal.

18 Secondly, I am a member of the board of
19 directors of Targeted Genetics Corporation right now,
20 and Targeted Genetics is perceived by some people to be
21 the leading gene therapy company in the world, and so
22 my experience as a director that -- of a -- quite an
23 active research-based company I think has some
24 relevance.

25 Then the third company that I've listed is a

1 very interesting company called First Horizon
2 Pharmaceutical Company, which is a company that was
3 just formed about two and a half years ago, went public
4 about a year and a half ago and has had its stock price
5 go from about \$8 at IPO to in the thirties now. I say
6 that only because it's been a successful company, but
7 the business of First Horizon Pharmaceutical Company is
8 very germane to this proceeding in that what it does is
9 in-license late stage, relatively small market
10 pharmaceuticals, develop them and market them. It has
11 a sales force to market its products. I'm chairman of
12 its Scientific Advisory Board and have been involved
13 with virtually all of the acquisition activities that
14 First Horizon has done since its inception.

15 Q. Moving away from your experience in the
16 pharmaceutical industry, can you tell us how many times
17 you've been retained to testify as an expert for
18 litigation?

19 A. Recently?

20 Q. The last five years.

21 A. Twice.

22 Q. Okay. And in the last five years, what
23 percentage of your time has been spent in work related
24 to testifying as an expert?

25 A. Oh, gee, 2 percent, 3 percent, something less

1 than 5 percent, well less than 5 percent.

2 MR. SILBER: Your Honor, based on Dr. Levy's
3 three decades of experience in the pharmaceutical
4 industry, in medicine, in teaching and in clinical
5 research, we submit him as an expert in the field of
6 pharmaceutical licensing and pharmaceutical valuation.

7 MS. SHORES: Your Honor, we would renew the
8 objections that we raised to Dr. Levy's testimony in
9 our motion in limine. As I understood the Court's
10 ruling with respect to Dr. Bresnahan, that's something
11 that the Court I anticipate will take into effect at
12 the end of his testimony.

13 MR. CURRAN: Your Honor, we join in renewing
14 our opposition to Mr. Levy being designated as an
15 expert in the area of pharmaceutical licensing for the
16 reasons stated in the motion in limine.

17 In addition, I would like to note that when
18 Your Honor dealt with that motion in limine at the
19 outset of the case, Your Honor I believe restricted the
20 scope of Mr. Levy's -- Dr. Levy's testimony, indicating
21 that he was -- he could not opine on the credibility or
22 truthfulness of sworn testimony of executives of
23 Schering-Plough or Upsher-Smith.

24 JUDGE CHAPPELL: That's correct.

25 MR. SILBER: Your Honor, may I just add a word,

1 please?

2 JUDGE CHAPPELL: All right.

3 MR. SILBER: We are well aware of your ruling
4 regarding Dr. Levy, and I have shared that ruling with
5 Dr. Levy. I'd also like to note, however, that at no
6 point in Dr. Levy's expert report and at no point does
7 he intend to testify to the credibility of those
8 witnesses. His opinion is based upon his examination
9 of the facts and his experience in the industry.

10 JUDGE CHAPPELL: We don't need to belabor that
11 point. That's water under the bridge. I've already
12 ruled on that. I'm going to overrule the objections at
13 this time, and I'm going to allow the expert to testify
14 subject to objections that may arise based on the
15 questions you're going to ask him.

16 So, with that, you may proceed.

17 MR. CURRAN: Thank you, Your Honor.

18 MR. SILBER: Thank you.

19 BY MR. SILBER:

20 Q. Dr. Levy, what basic conclusion have you
21 reached regarding whether the \$60 million noncontingent
22 payment was for Niacor-SR?

23 A. I've prepared a slide --

24 MR. CURRAN: Objection. Objection, Your Honor.
25 That question necessarily calls for the witness to

1 opine as to the credibility of witnesses who have
2 testified uniformly that the \$60 million, I will ignore
3 for the moment the failure to discount, was not -- that
4 the witnesses in this case have all testified that the
5 \$60 million discounted was for Niacor-SR. This witness
6 cannot say otherwise. He can opine as to the
7 reasonableness of the amount, but he cannot opine as to
8 whether the payment was for Niacor-SR or not.

9 JUDGE CHAPPELL: Okay, I'm overruling that
10 objection. Under Rule -- Federal Rule 705, he does not
11 have to disclose facts or data underlying his opinion
12 on direct, but you have an opportunity to explore those
13 facts and data on cross examination. So, it's
14 overruled at this time.

15 MR. CURRAN: Thank you, Your Honor.

16 JUDGE CHAPPELL: You may proceed.

17 BY MR. SILBER:

18 Q. If I may just repeat the question.

19 Dr. Levy, what basic conclusion have you
20 reached as to whether the \$60 million noncontingent
21 payment was for Niacor-SR?

22 A. I've prepared a slide that I think summarizes
23 that opinion. May I have it, please?

24 Q. Certainly.

25 And if I may just note for the record that this

1 is CX 1597 encaptioned, "\$60 Million Was Not for
2 Niacor-SR."

3 Please go ahead.

4 A. I think the opinion is summarized in the black
5 bold type at the top. It is my firm opinion that the
6 \$60 million payment was not at all for Niacor-SR.
7 There are three basic opinions, if you will, that
8 underlie that overriding opinion. The first of these
9 was that the noncontingent, unrestricted \$60 million
10 payment was grossly excessive by virtually every
11 parameter that one can examine.

12 Secondly, the due diligence that led to the
13 company's making that payment was so superficial as to
14 defy description.

15 Thirdly, after the deal had been executed,
16 after the company had agreed to pay and indeed has paid
17 \$60 million, neither party did anything that even came
18 close to what I have ever seen, ever, in the behavior
19 of licensee and licensor regarding any in-licensed
20 product, never mind one for which they had paid \$60
21 million.

22 Q. Dr. Levy, let's discuss how you've reached
23 these conclusions, if we could start by you telling us
24 how you began your analysis.

25 A. Yes, and I'm trying to think back to, you know,

1 to just the initial phases. I think at the outset, you
2 sent me the -- I guess it's referred to as the
3 complaint, and I read that, and then I was -- I was --
4 I asked for or was sent, I don't remember how it came
5 about, the defendant or is it the respondents' -- I'm
6 not sure of the terms in this matter, I apologize --
7 had prepared a number of white papers, and I read them
8 because I really knew nothing about the facts in this
9 case and tried to -- really to look at the arguments
10 that each of the parties was presenting, and read them
11 and began to formulate some opinions but really had no
12 opinion at this point.

13 Then I was able to review a number of
14 depositions from various parties in the case and worked
15 through this over a period of, gee, six or seven months
16 in what I perceive as an iterative process in that I
17 really tried to look at the arguments that were being
18 presented by all the parties and to see if -- you know,
19 where the various and sundry bits of information, data
20 fell as I tried to formulate this opinion. And over a
21 period of several months, in reviewing all this
22 information, came to the conclusions that I've reached
23 here. But I would say it was an iterative process that
24 involved reviewing, you know, quite a large number of
25 documents.

1 Q. About how many documents?

2 A. Oh, goodness, I measure it in terms of volume,
3 and it's filling up a large part of my office.
4 Thousands of pages. I really don't -- I don't know how
5 many documents, but if one counts the boxes or if one
6 counts the volume, I would say it's -- it must be
7 10,000 pages or -- I don't know. It's just a huge
8 volume.

9 Q. And approximately how many depositions have you
10 read?

11 A. I've not counted them either, but I think it's
12 probably about 15.

13 Q. And approximately how many hours have you
14 worked on this matter?

15 A. I would say -- again, I apologize for not
16 having an exact accounting of that, but it's somewhere
17 between 350 and 400 hours I would think.

18 Q. And can you tell us what rate you're charging
19 the FTC for your services?

20 A. \$350 an hour.

21 Q. Dr. Levy, before going into your ultimate
22 opinion that the \$60 million was not for Niacor-SR and
23 the three subopinions there, if we could do a little
24 background on the drug involved.

25 Can you tell us what the Niacor-SR drug was

1 intended to treat?

2 A. Yes. May I have -- I've prepared a slide -- I
3 don't want to get too didactic here, but if I may have
4 that next slide.

5 Q. Certainly.

6 A. That would be helpful.

7 MR. SILBER: Your Honor, this is marked as
8 CX 1599, and it is labeled Classes of
9 Cholesterol-Lowering Drugs, Percentage of Total Sales,
10 1996.

11 THE WITNESS: Would it be possible for me to go
12 to the screen?

13 MR. SILBER: Sure. Your Honor, with your
14 permission?

15 JUDGE CHAPPELL: Yes.

16 THE WITNESS: What I've tried to do -- to
17 answer Mr. Silber's question, Niacor-SR was meant to be
18 one of a group of drugs to treat the broad condition of
19 what we refer to as hyperlipidemia, that is, I think we
20 generally think of it as high cholesterol, high blood
21 cholesterol. It's, of course, a little bit more
22 complicated than that, but that's close enough.

23 And just to put Niacor-SR in context without
24 trying to -- you know, to overdo this lecture, I think
25 it's important to see where it fits in the general

1 realm of cholesterol-lowering drugs. And these data
2 were actually derived from a document that was one of
3 the documents that I was presented that came from
4 Schering-Plough, and Schering-Plough got these data
5 from what I believe is the most accepted and most
6 widely used source of pharmaceutical sales data, IMS.
7 The year is 1996.

8 As you can see, by far, the largest market for
9 drugs that treat high cholesterol are drugs that are
10 referred to as the statins, and the statins are a group
11 of drugs that inhibit a specific enzyme, that's HMG-CoA
12 reductase. The significance of that is -- and the
13 reason I'll dwell on this a little bit is that the
14 statins, from the perspective of a guy who discovers
15 drugs for a living or has anyway, it -- are almost
16 perfect drugs in that this particular enzyme, HMG-CoA
17 reductase, catalyzes the rate-limiting step in the
18 synthesis by the body of cholesterol.

19 It converts a chemical called
20 hydroxymethylglutaryl into another chemical called
21 mevalonic acid, mevalonate, and mevalonate is a
22 precursor of cholesterol, but the key thing is that
23 this enzymatic step is what we refer to as rate
24 limiting. So, if you slow down that step with a drug,
25 you slow down the rate of synthesis of cholesterol in

1 the body, and you do it specifically.

2 So, the statins have just revolutionized the
3 treatment of high cholesterol in people, and it does
4 exactly what one wants it to do in that it raises the
5 level of HDL, high density lipoproteins, and it lowers
6 LDL, the so-called bad cholesterol. So, that's why
7 it's got 75 percent of the market. The market's
8 actually bigger than that now. They actually have a
9 bigger chunk of the market now.

10 BY MR. SILBER.

11 Q. Dr. Levy, are you familiar of with some of the
12 names under which the statins are marketed?

13 A. Yes.

14 Q. Could you give us a couple illustrations?

15 A. Yes, Zocor is one, you know, there's -- there's
16 five or six of them that are -- that are prominently
17 prevalent, so...

18 Q. Okay.

19 A. The other class -- and here it's 19 percent, I
20 think that percentage is probably lower now, which is a
21 class of drugs called the fibrates, and these drugs
22 antedated the statins and are not used as widely,
23 because first of all, they are not as efficacious, and
24 secondly, the mechanism is really not very clearly
25 understood, and thirdly, they have some adverse effects

1 that are -- that are unpleasant. They can cause
2 gallstones. They can cause a condition called
3 rhabdomyolysis, just some problems with them, but they
4 are still more widely used than any of the other drugs
5 here.

6 The third group is referred to as the bile acid
7 sequestrants, and these drugs act largely in the GI
8 tract, and to make -- to simplify things, they prevent
9 the absorption of cholesterol into the bloodstream, and
10 so they act in a very different way than either of
11 these others.

12 Now, niacin occupies a trivial share of the
13 market. Niacin is a vitamin. It was found several
14 years ago that very high doses of niacin can cause a
15 lowering of the bad cholesterol, of LDL, and also cause
16 somewhat of an elevation of HDL. So, they do good
17 things, but niacin has virtually unacceptable side
18 effects. Patient compliance with -- in taking niacin
19 for lowering cholesterol is virtually zero. That's why
20 it's so infrequently used.

21 And the reason for that is that it causes a
22 rather severe flushing reaction, that is, you get red
23 and itchy, and patients don't like to be red and itchy,
24 and so the frequency with which patients will comply
25 with taking niacin is -- is very small, particularly

1 when they have an alternative like the statins.

2 What went on -- and germane to Mr. Silber's
3 question to me about what is Niacor-SR -- was that the
4 industry has recognized that niacin does have some good
5 effects in terms of lowering LDL and increasing HDL
6 particularly, and so they hoped that they could find a
7 way to present niacin in doses where it would be
8 efficacious but where this flushing side effect would
9 be -- would not be a problem. And so the theory was
10 that if you give the niacin very slowly rather than
11 giving in a pill a big bolus, that the -- you'll get
12 the good effect and you won't get the flushing effect.

13 And so there was some sustained release or slow
14 release forms of this drug that were prepared. And for
15 reasons that I don't think are understood, and I
16 certainly -- I know I don't understand them, these slow
17 release forms were found to be toxic to the liver, and
18 so they never got -- they never saw the light of day.
19 They were never approved. They were not used just
20 because they had this liver toxicity.

21 Well, Niacor-SR was an attempt to do this; that
22 is, to release niacin slowly into the bloodstream and
23 obviate this flushing side effect. That's -- I'm
24 sorry, that's a long-winded answer to Mr. Silber's
25 question of what is Niacor-SR. So, Niacor-SR is an

1 attempt to deliver niacin in a dose that will lower
2 cholesterol and in a way that will not have side
3 effects.

4 Q. Dr. Levy, you've talked about the sustained
5 release forms of niacin. Are you familiar with a
6 sustained release niacin that's on the market now?

7 A. Yes, I am.

8 Q. And what is that drug?

9 A. Niaspan.

10 Q. Okay. If we could have the next slide, which
11 is CX 576.

12 This was a slide that I believe Dr. Bresnahan
13 used in his presentation in which he indicated that he
14 relied upon your report, and what I'd like you to do is
15 simply kind of walk us through Dr. Bresnahan's slide
16 and share with us your opinion on the different
17 characteristics he looked at.

18 A. Okay. Well, I mean, both drugs are listed and,
19 you know, Kos is the manufacturer of Niaspan. Product
20 type, I agree that they're both intended to be
21 sustained release forms of niacin. Therapeutic
22 efficacy, there are some subtle differences between
23 them, but I think that that's fine. I mean, to say
24 that they are equivalent in -- from the perspective of
25 efficacy, again, I think is a reasonable statement.

1 Dosage, Niaspan has a very considerable
2 advantage over Niacor-SR. Niaspan was studied and is
3 sold as a once-a-day drug. Niacor was a twice-a-day
4 drug. Remember, what we're talking about here is
5 patient compliance. A big deal in the pharmaceutical
6 industry is to go from being a four-times-a-day drug to
7 a twice-a-day drug or a twice-a-day drug to a
8 once-a-day drug, because patients simply have a much
9 higher level of compliance the more frequent -- the
10 more infrequently a drug has to be administered, and so
11 having a once-a-day drug as opposed to a twice-a-day
12 drug was a very considerable market advantage.

13 Side effects to me represent one of the truly
14 major differences between these two drugs. Niaspan did
15 seem to diminish, certainly didn't eliminate, this
16 flushing problem. To show you how bad the flushing is,
17 Niaspan was effective in diminishing this flushing, but
18 it still caused flushing in 88 percent of patients.
19 So, that's better than 98 percent, but -- so, it -- and
20 it also diminished the intensity of the flushing, but
21 it was still -- it still had plenty of problems.

22 But the key thing about Niaspan was that it did
23 not have the apparent liver toxicity that had been seen
24 with the previous attempts to make a sustained release
25 niacin, and so it succeeded in that regard. And

1 Niacor-SR did not. Niacor-SR in the scant data that
2 I've seen, and for that matter Schering-Plough has
3 seen, had absolute and clear evidence that would
4 suggest hepatotoxicity.

5 The licensed area for Niaspan was -- Niaspan
6 was available worldwide. Niacor-SR was only available
7 in the non-NAFTA countries, and for Schering-Plough,
8 who has -- although it's an international company, its
9 presence in the Far East is not very strong compared to
10 other major pharmaceutical companies. Its principal
11 international presence among the two major markets,
12 that is, the Far East and Europe, is in Europe. And so
13 Niaspan being available worldwide, Niacor-SR being
14 available non-NAFTA but essentially in the EU I think
15 is an advantage of Niaspan.

16 Regulatory approval, Niaspan was approved
17 approximately a month after the deal that we're talking
18 about here, the license agreement between the two
19 parties was executed. So, Niaspan was approved in
20 either July or August of 1997 and has been on the
21 market since.

22 The final element was one that was raised by
23 the respondents, and that was the fact that in the very
24 early and essentially preliminary negotiations or
25 discussions that went on between the -- between Kos and

1 Schering-Plough, Kos was indicating that it wanted, in
2 order to give the license to Schering for the U.S., it
3 wanted what they referred to as a primary detailing.
4 That is, that when the salesperson calls upon the
5 physician, the first thing he pulls out of his bag
6 would be Niaspan , and this was something that was not
7 acceptable to Schering since it has other drugs that it
8 might like this guy to pull out of his bag first.

9 Now, remember, this was only for the U.S.
10 market where this -- where this issue was raised. It
11 had nothing to do with what would or would not have
12 been done in the European market. So, I list this as
13 an advantage, but it's probably moot in terms of the
14 issues in this case.

15 And then finally, the \$60 million noncontingent
16 payment was indeed paid by Schering-Plough for this
17 product. I think there's testimony that would suggest
18 that no unrestricted noncontingent payment would have
19 been required were Schering to have indeed gone forward
20 and chose to license Niaspan.

21 Q. Dr. Levy, going through these characteristics,
22 you talked about the regulatory approval status for
23 Niaspan, indicating that a month after the June '97
24 deal with Schering and Upsher, that product was
25 approved. I think you failed to give us information on

1 the regulatory status of Niacor at the time of the
2 deal, if you could just elaborate on that.

3 A. At the time of the deal?

4 Q. Yes.

5 A. It was -- well, what Upsher-Smith represented
6 was that it was ready or would be ready to file what's
7 referred to as a new drug application with the U.S.
8 Food and Drug Administration in December of 1997; that
9 is, approximately six months after the deal was
10 executed. That -- and Schering-Plough then intended to
11 use that U.S. filing in support or partial support of
12 the filings that it intended to make in the European
13 Union.

14 Upsher-Smith never came close to making that
15 NDA filing and indeed but a few months after this deal
16 was executed abandoned the project.

17 Q. Thank you.

18 Your Honor, I'm about to start to go more into
19 a substantive opinion. We can continue or if you would
20 like to take a break at this point.

21 JUDGE CHAPPELL: It's about 11:05. Let's take
22 a 15-minute recess.

23 MR. SILBER: Thank you.

24 (A brief recess was taken.)

25 JUDGE CHAPPELL: Let's reconvene docket 9297.

1 You may proceed.

2 MR. SILBER: Paula, if I could have the slide
3 summarizing Dr. Levy's opinion. Actually, we had set
4 this up so that other points were supposed to be grayed
5 out, and I continue to see them. Let's go back to the
6 first slide so we can see them.

7 BY MR. SILBER:

8 Q. All right, Dr. Levy, getting to your
9 substantive opinion, you've shared with us that you've
10 reached the conclusion that the \$60 million
11 noncontingent payment was not for Niacor. Looking at
12 the first opinion under there, that the noncontingent
13 unrestricted \$60 million payment was grossly excessive,
14 if we could start by going through some terminology,
15 and if you could discuss with us the general terms that
16 are used in licensing deals for pharmaceuticals.

17 A. The general terms? I'm not sure I understand.

18 Q. The different types of payments.

19 A. Oh, oh, I'm sorry. Yes, I actually prepared a
20 slide on that issue as well. May I have that slide?

21 Q. Sure, and this slide is CX 1602.

22 And Your Honor, with your permission, if Dr.
23 Levy could illustrate from the board?

24 JUDGE CHAPPELL: You may.

25 THE WITNESS: Sorry.

1 What I tried to illustrate here are the
2 components of -- the payment components that comprise
3 the typical licensing deal, and there are three major
4 groups or types of payments that are typically
5 associated with any licensing transaction. I'll go
6 through each of them, if I may.

7 The first of these I refer to as licensing
8 consideration, and I'll come back to that in a moment
9 with a little bit more discussion.

10 Milestone payments are quite different from
11 licensing consideration. Milestone payments are
12 contingent upon performance. They may be, for
13 instance, linked to the filing of a registration
14 document, like a new drug application; the approval of
15 that document in various markets. They may be -- those
16 payments may be linked to the products reaching a
17 certain level of sales, \$200 million, \$300 million,
18 \$500 million, but the key thing is those payments are
19 contingent upon some element of performance, either by
20 the licensor or by the product or both.

21 And then thirdly, royalty payments which are
22 simply a percentage typically of the net sales of the
23 product in the various markets in which it's licensed.

24 Going back to the first of these, I think these
25 are the sort of distinctions that I'd like to try to

1 make clear, if I may, because they're quite germane to
2 the major matter at hand. Within this broad category
3 that we refer to as licensing consideration are three
4 types of payments, and they're very different.

5 The first of these are simply cash licensing
6 fees. This is the type of fee that was paid in this --
7 that's the subject of this discussion. The \$60 million
8 payment was a cash, noncontingent fee, licensing fee,
9 and the only thing that the licensee got for that was
10 the opportunity to do the deal, and it was -- and there
11 were no strings attached to it, if you will, other than
12 signing the document.

13 Now, a second is an equity investment. Very
14 frequently in transactions between a large company and
15 a small company, it behooves the small company to have
16 the large company make an equity investment in it. Two
17 things happen to the small company in this situation.
18 First, they get the credibility of the large company,
19 in this case say Schering-Plough making an equity
20 investment in the small company, it gives it
21 credibility in the marketplace, and secondly, it, of
22 course, brings cash into the company for the sale of
23 that stock.

24 But what's key here is that the licensee, the
25 payer, also gets something, it gets stock. So,

1 regardless of what happens to the deal, regardless of
2 what happens to the drug, this stock has value, and I
3 can give you a very interesting personal experience
4 with that.

5 When I was at Abbott, I was involved with a
6 deal that Abbott did with AMGen. AMGen is now by far
7 the most successful of all the biotechnology companies.
8 It has a huge market capitalization. Well, Abbott did
9 a deal with AMGen where it got for a \$5 million equity
10 investment 6 percent of the company. It also got as
11 part of this transaction the right of first negotiation
12 on the first two of AMGen's products.

13 What's significant here is that Abbott was not
14 able to out-bid, for instance, Johnson & Johnson for
15 one of AMGen's exciting products. So, it didn't get
16 the product, but it still got the equity. I believe it
17 was seven years later, Abbott sold this \$5 million
18 worth of stock for I believe it was \$465 million. So,
19 they did okay on that deal regardless of their not
20 having gotten the drug.

21 And indeed, as we'll see later in some of the
22 analogous transactions that Schering-Plough has done
23 where it bought as part of the licensing transaction
24 equity in the company, that equity has increased in
25 value considerably. So, bottom line is they got

1 something other than just the opportunity to do the
2 deal.

3 The third one that's also under licensing
4 consideration is research support. Often times, and
5 certainly it's the case here, the product or products
6 that are licensed require some additional research to
7 be done, typically clinical research, and this research
8 can be done by the licensee, by the large company, but
9 sometimes it behooves the licensee to pay the licensor
10 to do the research.

11 Now, this is a good deal for the licensor as
12 well, because it gets money, it gets some of its people
13 paid for, but it's a great deal for the licensee as
14 well, because that research had to be done, whether it
15 was paid for and done by their own internal employees
16 or this money was used to pay for the licensor's people
17 to do it. They're getting something for this money.
18 It's not just, you know, a check being written with no
19 strings attached.

20 May I have the next slide, please?

21 Q. Sure.

22 A. This one --

23 Q. Let me just introduce this as CX 1602 labeled
24 as Deal Size.

25 A. This I think introduces a term that I've

1 certainly come across frequently in my reading some of
2 the respondents' documents here, and I want to
3 introduce it at this time, lest there be any confusion
4 about what these terms mean. The fee that we're
5 talking about in this case is this one, cash licensing
6 fees. That's what the \$60 million was. There were no
7 contingencies attached to it whatsoever. The check was
8 written or the checks were written, and that's -- and
9 that was it.

10 Deal size is a very, very different term. It
11 includes all three elements of licensing consideration
12 plus all the milestone payments, and as I've tried to
13 illustrate here, the milestone payments in almost every
14 licensing deal are much larger than the license fees,
15 and indeed, in virtually every one of Schering's other
16 transactions that we'll discuss today, the milestone
17 payments were considerably larger than the license
18 fees. And so I don't want the Court to be confused by
19 using -- by confusing this term, "deal size," with this
20 term, "cash license fee," or "noncontingent,
21 unrestricted license fee."

22 Q. And Dr. Levy, these three areas, licensing
23 consideration, milestone payments, royalty payments,
24 these are the major payment terms that are subject to
25 negotiation when parties are negotiating a

1 pharmaceutical license?

2 A. Yes, sir.

3 Q. Okay. And from a licensee's perspective, what
4 does a licensee prefer? Does it prefer to have
5 noncontingent payments generally or does it prefer to
6 have milestone payments?

7 A. Well, this is always -- I mean, this is a
8 subject of negotiation. The -- the licensee always
9 wants to pay little or nothing in the license fee. The
10 licensor, of course, would like to get as much cash up
11 front as it can get with as few strings attached to it
12 as it possibly can get.

13 The only time when license fees rise above a
14 fairly -- a very low level is when there is
15 considerable competitive activity for this -- for this
16 product and when the product has enormous upside
17 potential. Even then, the license fees are kept at a
18 modest level compared to the overall size of the deal
19 and compared to the sales potential and earnings
20 potential and cash flow potential of a licensed
21 product.

22 In contrast, milestone payments are often very
23 generous, because pharmaceutical companies --
24 pharmaceuticals, branded pharmaceuticals, are very
25 profitable. Once the product is approved and we can

1 get in the market with it, we're -- we're more than
2 happy to share the benefits, if you will, with the
3 licensor, with the originator of the product, and so,
4 for instance, in this country, one can easily see
5 milestone payments upon the approval of an NDA \$20,
6 \$30, \$40 million, but that's -- you know, you're on the
7 doorstep of making money with the drug then. It's
8 very, very different.

9 Q. A moment ago when you were describing what kind
10 of drives up the noncontingent payments, you used the
11 term "competitive activity." Could you elaborate on
12 that a bit, what kind of competitive activity there is?

13 A. Well, for -- for instance, for some of the
14 products that Schering-Plough itself has licensed in
15 other transactions, there are a number of other
16 companies that had an interest in licensing these
17 products. I've certainly seen that in some of the
18 licensing transactions with which I've been involved,
19 and I mentioned one a moment ago with AMGen where, you
20 know, Abbott would have loved to have gotten
21 erythropoietin, but Johnson & Johnson got it because
22 Johnson & Johnson really had more to offer in various
23 aspects of the auction, and it's really a function of
24 there being some competitive pressure on the parties.
25 And one of the main things that one can negotiate to

1 make your offer more attractive is more money up front
2 in the form of a license fee.

3 Q. Now, we've been talking in general about how
4 licensing deals are structured. In your work in this
5 matter, have you had the opportunity to look at
6 Schering's licensing transactions to see how they
7 structure noncontingent payments versus milestone
8 payments?

9 A. Yes, I have.

10 Q. Can you describe for us in general what you've
11 learned?

12 A. In general, with the exception of this
13 transaction, all of Schering's other license -- license
14 deals look just like all the other deals that I've seen
15 throughout the pharmaceutical industry.

16 Q. Now, let's turn to the specific deal in issue
17 here, the Niacor-SR deal. Can you describe for us how
18 that deal's payments were structured?

19 A. Yes, I think there's a slide on that as well,
20 if I may.

21 Q. And just to note for identification, this is
22 CX 1601 titled Niacor-SR Deal Terms.

23 A. Yes. Simply stated, the licensing
24 consideration was by far the dominant element of
25 payment in this transaction. There was a \$60 million

1 cash unrestricted, noncontingent fee that was paid in
2 three separate installments, \$28 million upon signing,
3 \$20 million one year after execution, and \$12 million
4 two years after that.

5 The milestone payments were -- well,
6 potentially could have totaled \$10 million. Now, these
7 milestone payments were each contingent upon the
8 approval of Niacor-SR in various foreign jurisdictions.
9 There was, if I remember correctly, a million dollar
10 payment due for each of the six or seven European
11 countries. There was a million dollar payment due upon
12 approval in Latin America, and there was a \$2 million
13 payment due upon approval of Niacor-SR in Japan, and
14 that totaled \$10 million.

15 Then the royalties were, again, very typical
16 for a transaction like this. A 10 percent royalty was
17 called for with the first \$50 million in sales, and
18 were the product to achieve \$50 million in sales, 15
19 percent royalty on the excess beyond that. I would say
20 that these two elements were very typical of a
21 licensing transaction and, you know, these two parts
22 looked exactly like any license deal, a license deal
23 for a product like this.

24 Q. What about the \$60 million noncontingent
25 payment?

1 A. This was just totally out of whack with any
2 reality I could imagine.

3 Q. Okay. When we had your slide up before with
4 your first point on the size of the payment, you used
5 the term "grossly excessive." What factors led you to
6 that conclusion that the payment was grossly excessive?

7 A. I think two types of facts. The first was that
8 on an absolute basis, the \$60 million payment was
9 larger than anything I had ever seen up to that time
10 for any drug, and on top of that was the fact that on a
11 relative basis, this drug was at best a minor drug, and
12 when one looks at it in the context of pharmaceutical
13 opportunities in general, it was -- it had, you know,
14 very low value.

15 If you will, I think there's a slide that
16 illustrates this a bit, if I may have the next one.

17 Q. And this slide is marked as CX 1603 labeled Top
18 500 Drugs in 2000, Worldwide Sales.

19 A. Just to put this in perspective, what I've done
20 here on the left side of this slide is to list the top
21 15 drugs' worldwide sales, and --

22 Q. Actually, Dr. Levy, if I may, before we go into
23 this in detail, can you tell us what this is based
24 upon, what the survey was for this data?

25 A. Yes, one of the -- one of the more useful

1 publications in our industry has the odd name of MedAd
2 News, and they -- it's a monthly publication that is
3 quite likely read throughout the branded pharmaceutical
4 and even generic pharmaceutical industry, that once a
5 year they have a whole issue devoted to the sales of
6 the various drugs, both listing them all together, as
7 this, and then they break out the various drugs into
8 different classes, anti-infectives, anticancer,
9 neurologic and so on. So, it's a very useful and I
10 think a very authoritative publication.

11 Q. I'm sorry, proceed, please.

12 A. Fine. Okay, shown here, just to put this all
13 in context, are the sales of the top 15 drugs, and as
14 one can see, the number one selling drug, Prilosec,
15 which is a drug to treat GI disease, had sales in 2000
16 of over \$6 billion worldwide. Number two and number
17 three, by the way, are statins, Zocor and Lipitor.
18 Interestingly again, number five is Schering's by far
19 biggest selling drug, and that's Claritin, selling \$3
20 billion worldwide. So, these are big drugs.

21 Now, over here, what I've tried to do is just
22 to put in context Niacor-SR in this realm, and what
23 I've done is taken the most optimistic number that the
24 parties have ever presented in this case; that is, \$140
25 million of annual sales for Niacor-SR. I might say

1 that several experts in this case, including some of
2 Schering-Plough's own executives, have doubted that
3 sales would ever reach more than \$50 or \$60 million.
4 That fact notwithstanding --

5 MS. SHORES: Your Honor, I -- I'm sorry, I
6 would object to his -- unless he is going to lay a
7 foundation for that, I would object to his summarizing
8 what he believes the evidence is as to that. There is
9 no foundation.

10 MR. SILBER: I am happy to withdraw that
11 statement. I think Dr. Levy can just testify to the
12 slide.

13 THE WITNESS: I apologize if I said something
14 out of line --

15 JUDGE CHAPPELL: Hold on, sir.

16 THE WITNESS: Yes.

17 JUDGE CHAPPELL: There's an objection pending.

18 Are you withdrawing the objection if he's
19 withdrawing the question?

20 MS. SHORES: If he -- if the Court will strike
21 his testimony in that regard, I will withdraw the
22 objection.

23 JUDGE CHAPPELL: I will disregard it.

24 MS. SHORES: Fair enough.

25 JUDGE CHAPPELL: Thank you.

1 MS. SHORES: Fair enough, Your Honor.

2 JUDGE CHAPPELL: You may proceed.

3 BY MR. SILBER:

4 Q. Please proceed.

5 A. At any rate, the \$140 million number came from
6 Mr. Audibert's projections on the sales of this drug,
7 and his peak sales reached \$140 million, and that's the
8 number I chose. And that fact notwithstanding, this
9 drug still wound up below number 300. So, here it is
10 with the largest noncontingent payment of which I am
11 aware up to that time, and it -- for a drug that at
12 best would have ranked number 305 or something.

13 Interesting to me, when I prepared this slide,
14 I didn't do it on purpose, there's a drug called
15 amBisome, which happens to be a drug that I in-licensed
16 for LyphoMed and had responsibility for studying and
17 ultimately was sold and is sold today by Fujisawa. The
18 up-front, noncontingent payment on the deal that I did
19 was zero. The milestone payments were \$4 million for
20 amBisome, which actually ranked a couple of ranks above
21 Niacor-SR, just to put this in perspective.

22 Q. Okay. Dr. Levy, this shows -- this slide, this
23 MedAd survey you're using, shows worldwide sales. Now,
24 sales figures for Niacor were ex-NAFTA, meaning outside
25 of U.S., Canada and Mexico. Why did you use worldwide

1 sales here?

2 A. Worldwide sales are the numbers that are --
3 well, there's two types of numbers that are fairly
4 readily available in these types of publications, U.S.
5 sales and worldwide sales. Typically as sort of a
6 ballpark figure in our industry, we make the assumption
7 that U.S. sales are roughly half of the worldwide
8 sales. They're now a little bit less than that, but
9 that's -- that's -- that's a reasonable approximation,
10 and the rest of the world is viewed as the other half,
11 and of that, roughly a third is viewed to be the Far
12 East, principally Japan, and two-thirds the European
13 Union. Again, those are approximations, but I thought
14 that the worldwide sales numbers are the most
15 authoritative.

16 Q. Okay. Dr. Levy, in concluding that the \$60
17 million noncontingent payment was grossly excessive,
18 have you analyzed specific Schering licensing
19 transactions?

20 A. Yes, I have.

21 Q. And what transactions have you looked at?

22 A. I believe -- well, initially we had in our --
23 we had 13 license agreements on various transactions
24 that had been provided to the Federal Trade Commission
25 by Schering-Plough, and I read all of those license

1 agreements and summarized the terms of them in my
2 report.

3 Subsequent to that, we have received further
4 information from Schering-Plough which included
5 summaries of all of their transactions, which I believe
6 numbered 33, where more than a million dollars was paid
7 in noncontingent fees, and I looked at the summaries of
8 those and any other information that we could get on
9 those 33 different Schering-Plough agreements.

10 MR. SILBER: Your Honor, at this time I'm going
11 to use part of Dr. Levy's report. His report has been
12 designated in camera, and I think in particular because
13 of this information which summarizes some of the deal
14 terms for Schering's other licensing transactions, so I
15 think it would probably be appropriate to go in camera
16 at this point.

17 JUDGE CHAPPELL: All right, Counselor.

18 At this time, the public is going to have to
19 vacate the courtroom. We are going to cover some
20 information that has been ruled to be in camera or off
21 the public record. So, if you're not subject to the
22 protective order entered in this case, you'll need to
23 leave at this time. We will have someone notify you
24 when we're open to the public again.

25 (The in camera testimony continued in Volume 7,

1 Part 2, Pages 1457 through 1491, then resumed as
2 follows.)

3 BY MR. SILBER:

4 Q. If I could have the slide with the summary of
5 Dr. Levy's opinion?

6 Dr. Levy, at this point we've reviewed the
7 agreements and the summaries of Schering's licensing
8 agreements that you have reviewed, and from the review
9 of those materials, what is your opinion regarding
10 whether the \$60 million noncontingent payment was for
11 Niacor-SR?

12 A. I would say that the payment of \$60 million was
13 so grossly excessive that I would not think it could
14 reasonably have been for Niacor-SR and the associated
15 generic drugs.

16 Q. Okay. Now, in that point on your slide where
17 it says the noncontingent, unrestricted \$60 million
18 payment was grossly excessive, you refer to the
19 payment, the \$60 million payment, but you don't refer
20 to the milestone payments or the royalty payments. Why
21 is that?

22 A. Interestingly to me, I said assuming that I
23 were to have completed due diligence on this product
24 and assuming that I wanted to license it, assuming --
25 and those are bold assumptions, but that -- making that

1 stipulation, this deal looks to be a perfectly normal
2 deal if you just take away that \$60 million balloon.

3 The \$10 million in milestone payments with a
4 million dollars for the approval in each of the major
5 jurisdictions, with the exception of Japan where it was
6 \$2 million, is perfectly in line with the sort of
7 milestone payments that I would see and others have
8 seen for deals for products like this.

9 The 10 percent royalty going to 50 percent
10 royalty at a certain sales level of \$50 million, again,
11 is perfectly consistent and normal, if you will, within
12 the context of the agreements that I've seen and within
13 the context of the other agreements that -- that
14 Schering has entered into. It's just the license fee
15 that was grossly out of line.

16 MR. CURRAN: Your Honor, I have an objection
17 and a motion to strike. A moment ago, Dr. Levy
18 opined -- this is on page 110, lines 12 through 15 of
19 the realtime transcript -- that the \$60 million in his
20 opinion could not reasonably have been for Niacor-SR
21 and the associated generic drugs. Your Honor, there's
22 no foundation for that opinion as it affects -- as it
23 relates to "associated generic drugs," and that exceeds
24 the scope of Dr. Levy's purported expert testimony.

25 JUDGE CHAPPELL: I'll sustain the objection as

1 to other associated drugs. We have heard nothing from
2 Dr. Levy on that matter.

3 MR. SILBER: Okay. Your Honor, I apologize,
4 it's -- the testimony is probably less than clear on
5 this point. I believe that Dr. Levy's opinion does
6 encompass those drugs, and, in fact, that's what he
7 stated in his expert report. If you would like, I'd be
8 happy to ask Dr. Levy a couple questions on that point
9 to clarify his opinion.

10 JUDGE CHAPPELL: Well, as of right now, we have
11 no foundation for that.

12 MR. SILBER: Okay.

13 JUDGE CHAPPELL: So, if you would like it
14 considered, then I would suggest you do that.

15 MR. SILBER: Okay.

16 BY MR. SILBER:

17 Q. Dr. Levy, in conducting your analysis in this
18 matter, did you consider whether the \$60 million
19 payment was appropriate for Niacor-SR and the
20 associated generic drugs that were licensed?

21 A. Yes, I did, and as you stated a moment ago, I
22 did state that in my -- in my written report. I read
23 the whole license agreement and looked at each of the
24 products that were covered. If I remember correctly,
25 in addition to Niacor-SR, there were three other

1 generic drugs that were included in this license
2 agreement, and one of those generic drugs, potassium
3 chloride, was included in three dosage forms. So,
4 three different drugs, five different products.

5 And in my opinion, the -- first of all, license
6 fees and milestone payments and these types of payments
7 are just not part of generic drug transactions in my
8 experience in that generic drugs, unlike branded drugs,
9 have very different sales potential, very different
10 profitability, and from the point of view of licensing,
11 particularly since these drugs themselves, these
12 generic drugs, were relatively minor players in the
13 world of generic pharmaceuticals and there were many,
14 many other generics on the market.

15 For each of these, I thought that the -- the
16 value of these drugs was de minimus and that the major
17 value, if there was any, in this license agreement was
18 in Niacor-SR.

19 Q. Thank you.

20 Your Honor, at this time we have gone through
21 the first point of Dr. Levy's opinion. We could embark
22 on the second point. I expect that testimony to take
23 about an hour and a half, and with your indulgence,
24 could we consider doing a lunch break now?

25 JUDGE CHAPPELL: Yes, it's a good time. We're

1 at about 12:45. We'll break until 1:30.

2 MR. SILBER: Thank you, Your Honor.

3 (Whereupon, at 12:45 p.m., a lunch recess was
4 taken.)

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1 AFTERNOON SESSION

2 (1:36 p.m.)

3 JUDGE CHAPPELL: Back on the record, docket
4 9297.

5 You may proceed.

6 MR. SILBER: Thank you, Your Honor.

7 BY MR. SILBER:

8 Q. If I could have the slide summarizing Dr.
9 Levy's opinion, please.

10 Doctor, we have now gone through your first
11 point that the \$60 million payment was not for
12 Niacor-SR. We can now go through the second point, the
13 due diligence was strikingly superficial. What do you
14 mean by "strikingly superficial"?

15 A. It just fell dramatically short of any
16 evaluation process that I've encountered for a
17 pharmaceutical of this type in either my personal
18 dealings or for that matter those dealings that I have
19 observed other parties doing.

20 Q. Can you describe for us how you reached this
21 conclusion?

22 A. Well, I think first I really just recapitulated
23 in my mind the types of processes that I'm accustomed
24 to going through and then put the due diligence in this
25 case in some context, and I -- I remember when I read

1 Mr. Audibert's deposition and a few other parties'
2 deposition and the exhibits associated with that
3 deposition, I was frankly incredulous that this was all
4 there was, and in -- I think I used this term before,
5 and I don't want to overuse it -- but in this iterative
6 process that I've tried to follow, I actually asked you
7 and your colleagues for the rest of it so that I could
8 make this evaluation in some sort of, you know,
9 reasonable fashion, and we all came to the conclusion
10 that that's what there was.

11 And what I was trying to do was to put myself
12 back in the position in mid-June of 1997 without trying
13 to have information that was not available to the
14 parties at the time and essentially try to ascertain
15 what I might have done had I seen what they saw, and I
16 wanted to see everything that they had seen. So, I
17 asked for more information, and then when I think I,
18 you know, got all there was, came to this conclusion.

19 Q. Before going into what was done on this deal in
20 more detail, have you prepared a slide that summarizes
21 your experience in the industry as to how due diligence
22 generally proceeds for a pharmaceutical license?

23 A. Yes, I have.

24 Q. If we could have CX 1606, which is labeled
25 Pharmaceutical Licensing Evaluation Process, and if we

1 may, Your Honor, if Dr. Levy could approach the board
2 and walk us through this process?

3 JUDGE CHAPPELL: Okay.

4 THE WITNESS: What I've tried to do is just to
5 outline the general process that, you know, I'm
6 accustomed to, that I've been involved with and that
7 I've seen virtually all the other companies that I've
8 had anything to do with follow, recognizing that these
9 are generalizations and some of the time frames are
10 different and some of the boxes are in slightly
11 different orders, but this is a pretty strong framework
12 or general framework.

13 What's typically done, what I've labeled as
14 this first box is the preliminary evaluation, and the
15 way this generally works -- and indeed, I believe,
16 worked in several of the deals that we will look at
17 that Schering has engaged in -- the first thing that
18 happens is that the licensor, that is, the party that
19 has something to license, prepares a simple dossier,
20 usually with nonconfidential information in it that
21 describes the general nature of the product, what it
22 has, what stage it's at and so on, and this is usually
23 a, say, 5 to 30 page document, and the licensor sends
24 it to any potential licensee that he or she thinks
25 might be interested, and this almost always goes to the

1 department of the licensee that has various names, but
2 it could be licensing or business development. Those
3 are the two most common names for this type of
4 enterprise.

5 What happens during this preliminary evaluation
6 is one of the licensing officials looks at this
7 information with a couple of things in mind. First,
8 the first screen typically is does this fit our
9 company? For instance, if this is a drug coming in to
10 treat high blood pressure and it's a company like, say,
11 Galderma that markets pretty exclusively in the
12 dermatology arena, it won't get past that. If it is,
13 say, a cardiovascular drug, so be it, and so on.

14 But if it comes in to a company like
15 Schering-Plough that has a much broader scope in the
16 pharmaceutical realm, it will -- that screen will
17 usually be passed, except -- so, then maybe the next
18 screen would be Schering-Plough will have interests in
19 different types of drugs. So, this is a company that
20 markets in the infectious disease area, for instance,
21 it has some presence in the cardiovascular area, for
22 instance, and -- and so a drug in one of those
23 categories at least would get past the first screen.

24 Then the licensing official will look rather
25 superficially at all of the elements that will go into

1 the potential of this being a successful deal. You
2 know, does the drug look like it's new? Does the drug
3 look like it -- preliminarily, looks like it works and
4 is safe, or whatever information he has, and is there a
5 patent position? He won't investigate a detailed
6 patent position, but is there a patent or is there not
7 a patent? And then he often will make some preliminary
8 inquiries with some of his colleagues, his in-licensing
9 colleagues within the company, just for an opinion.
10 This is all a preliminary evaluation.

11 If it looks good to him at this point, then he
12 likely will ask the licensee or the licensor, I mean,
13 for a confidential disclosure agreement, and so then
14 they enter into an agreement that enables the licensor
15 to send a little bit more information, maybe a summary
16 of the clinical trial results, maybe some manufacturing
17 information, again, a little bit more information,
18 still at a preliminary stage, but now the licensing man
19 can make a little bit more informed decision about
20 whether he wants to go forward.

21 Then typically the third step in this kind of
22 preliminary evaluation is for there to be an -- you
23 know, a face-to-face meeting between the parties.
24 Typically, the licensee's licensing executive will make
25 a trip to the licensor's place of business,

1 particularly if he's not familiar with that company.
2 He wants to see what this place looks like, what kind
3 of operation do they have, just -- and then he wants to
4 meet the parties face to face, because so far all
5 they've done is exchange documents, and at that point,
6 they may also have some -- just some preliminary
7 discussions about what the parties want, not
8 negotiations at this point typically, but just to see
9 if they're in the same ballpark.

10 And if it gets past that stage and if he's
11 still interested, then this fellow or one of his
12 colleagues in the licensing department will essentially
13 become the quarterback for the deal, and he then will
14 try to shepherd this process or shepherd this drug
15 through the remainder of the company's evaluation
16 process. And typically this preliminary evaluation,
17 the sort of thing that I just spoke of, which is itself
18 a bit iterative, you know, takes somewhere between a
19 month and two or three months. Here I've shown it to
20 be about six weeks or so.

21 Q. Dr. Levy, so everything you've been speaking of
22 to this point is solely that first box, preliminary
23 evaluation?

24 A. Yes, sir, yes, sir.

25 Q. And in your experience, how many people are

1 usually involved from the licensee's side in conducting
2 a preliminary evaluation?

3 A. Oh, it can be one person. Usually he talks
4 with his colleagues. He may talk with somebody in R&D.
5 He may talk with somebody in marketing just to get a
6 feel, to bounce his ideas, but a small group.

7 Q. Okay. Then it goes on to the next step?

8 A. Yes, sir.

9 Q. If you can continue.

10 A. The next box, and as I said before, sometimes
11 these go in different order, this fellow in the
12 licensing department, this quarterback, if you will,
13 will typically identify the general areas of question
14 about this product, but almost always -- not always,
15 but almost always -- the next step is research and
16 development.

17 And here it goes to the -- the quarterback
18 takes it to the R&D director or the R&D director's
19 administrator and tells him about the product, tells
20 him about his level of enthusiasm for the product, and
21 now wants the R&D people to assign their real experts
22 in this field to look at the various facets of this
23 drug, so that the licensing guy -- I mean, he's an
24 experienced pharmaceutical man, you know, he knows that
25 a drug has to be safe and effective, he knows the

1 general classes of drugs, he's a knowledgeable
2 generalist, if you will, but he's not the guy to
3 evaluate a clinical trial, he's not the guy to evaluate
4 drug safety, he's not the guy to evaluate
5 manufacturing, et cetera, et cetera. It goes to the
6 experts.

7 So, within R&D, there will be one or two or
8 three people who evaluate the pharmacology, somebody
9 who evaluates the chemistry, somebody who evaluates the
10 toxicology, several people who will evaluate the
11 clinical trials, look at the protocols for the clinical
12 trials, look at how the trials will be conducted. And
13 then they almost invariably, within R&D, after they've
14 looked at this information, including the confidential
15 information, will make a site visit, and this will
16 usually be comprised of, depending on the information
17 they are going to look at it, these scientific experts
18 in this field.

19 So, for instance, a drug that had been through
20 Phase III clinical trials, like Niacor-SR, where there
21 supposedly is a lot of clinical data, all that had been
22 provided, that typically would have been provided as a
23 summary, but now these guys have to go to the site and
24 really look at the real McCoy. These guys have to look
25 at the data. They don't just look at, you know, a

1 two-page summary. They look at the data. They look at
2 how the data were acquired. They look at the -- they
3 will typically look at the raw data.

4 They want to look at what we call the case
5 report forms, because if they don't do it, they can be
6 sure the FDA will, and so if these case report forms
7 are inadequately filled out, if the data are not
8 properly processed, if there are holes anywhere, it
9 will come out in the FDA's audit, so you may as well
10 know that before you dive into this project.

11 So, you have experts, real experts, people who
12 do this for a living go and look at these data and come
13 forth with the problems, and there's always questions.
14 There's always questions that are raised in one aspect
15 or another, and one identifies those questions for
16 further investigation, and then in this iterative
17 process, the R&D person will say, you know, I'd like to
18 know more about this or I'd like to know more about
19 that, and they have the opportunity to question the
20 licensor's experts in this area, look at data, consult
21 their own experts, consult their colleagues in-house
22 and go through the process of trying to find out if the
23 data that exists on this product are sound and
24 supportive of the ultimate safety and effectiveness of
25 this drug so that it can be licensed as a

1 pharmaceutical.

2 JUDGE CHAPPELL: Do you have an objection?

3 MS. SHORES: Your Honor, I just wondered if we
4 might have more questions and answers. I don't know
5 that I would have any objections to Dr. Levy's
6 testimony in this area, but if I would, if I could at
7 least have the opportunity to make one.

8 JUDGE CHAPPELL: The objection's sustained.
9 We've got too much narrative going on here, Counselor.

10 MR. SILBER: Very well, Your Honor.

11 JUDGE CHAPPELL: Proceed.

12 BY MR. SILBER:

13 Q. Dr. Levy, you had mentioned experts in R&D that
14 are involved in this process.

15 A. Yes.

16 Q. What kind of training do those individuals
17 have?

18 A. Almost all of them have a doctorate degree.
19 The people who do the clinical evaluations are
20 typically M.D.s, although some of the most effective
21 ones I've encountered have Ph.D.s. So, it doesn't
22 require medical training, it requires a familiarity
23 with clinical research, but they almost all have
24 doctorates. And then the people who do toxicologic
25 evaluations and pharmacological evaluations and

1 clinical evaluations are almost always Ph.D.s.

2 Q. You had discussed the site visits that take
3 place in this process when the licensee goes and looks
4 at documents at the licensor's site. What type of
5 interactions take place between the parties in this R&D
6 review?

7 A. It's a pretty dispersive interaction. I mean,
8 confidential disclosure agreements have been executed
9 between the parties, and the R&D guys are in there to
10 find out anything and everything that they want to
11 know. I mean, they -- and so they will typically ask
12 the counterparts, their counterparts in the licensor's
13 organization, you know, to see this or if they have a
14 question about a certain study that was done, they will
15 want to look at that study.

16 If they're interested in, say, some animal
17 toxicology data, I've seen it often where they say I'm
18 going to look at the actual microscope slides. I want
19 to look at it. I don't want to take the word from even
20 your toxicologist. I want to go look at the slides.
21 I've seen that several times. So, as I said, it's an
22 interaction between the parties in an effort for the
23 licensee to discover -- to get his questions answered.

24 Q. Now, at this point we've gotten through the
25 preliminary evaluation, we've gotten through the

1 research and development review. How much time has
2 elapsed since the licensee first started looking at
3 this drug?

4 A. Oh, well, on this chart I think I've shown
5 about three months, and this is a fairly aggressive
6 schedule. This whole chart really assumes that this
7 product has been given high priority within the
8 company, where the licensing guy has enough clout in
9 the company and has enough excitement about the product
10 to say let's do this quickly, and, you know, to put it
11 through R&D in a month or two months is pretty
12 aggressive.

13 Q. Now that we're through R&D, on the next line
14 you have four boxes lined up side by side which are
15 financial, regulatory affairs, intellectual property
16 and commercial assessment. Why have you set these up
17 side by side?

18 A. Because they happen in a typical case more or
19 less simultaneously.

20 Q. Okay. And if you could start with the first
21 box there, financial, and tell us what type of review
22 is done there.

23 A. All right, well, up here, typically the
24 licensing person in this preliminary evaluation has run
25 a few preliminary numbers, I mean just to see if it --

1 pardon the vulgarity of it -- but just does it smell
2 right, does it make sense, does it fit, but he's not a
3 finance guy. He's not typically a person with a strong
4 financial background.

5 It goes down here to the professionals, the
6 people in the -- in the controller's office, in the
7 general financial areas of the company that can do the
8 detailed financial analyses looking at the myriad
9 financial factors that impact the financial decisions
10 regarding this product.

11 Q. And what type of background do these people who
12 do the financial review have?

13 A. You know, to be honest, I'm not as familiar
14 with what the finance people have as training across
15 the board. I know that many of them have CPA degrees,
16 and some of them have MBA degrees and some have both.

17 Q. Okay, let's move on to the next box, which is
18 regulatory affairs. What type of review is done there?

19 A. Yes, now, typically -- I've drawn these boxes
20 separately, but there's a lot of interaction that goes
21 on between regulatory affairs and research and
22 development in this matter, but just to sort of try to
23 keep it simplistic for explanation, the regulatory
24 affairs people are individuals who are expert in the
25 regulations that the various and sundry regulatory

1 jurisdictions impose upon the approval of a
2 pharmaceutical product.

3 They know the nuances of the regulations. They
4 know the types of information that will be required for
5 different types of drugs. They have their finger on
6 the pulse of the regulatory authorities, so they know,
7 if you will, what the changing winds are within the
8 offices, whether they be in Rockville, Maryland or in
9 foreign jurisdictions, and usually there's sort of two
10 groups here.

11 One deal with what we would refer to as
12 domestic issues, that is, people who are expert on FDA
13 issues, and then there is a separate group that have
14 expertise on foreign regulatory matters, and even
15 within those groups, there are people with specific
16 expertise on, say, some of the Far Eastern countries
17 and some of the European countries, because the bottom
18 line of all of them is that they're looking for the
19 drug to be safe and effective, but they approach this
20 question with slight differences, and one has to know
21 the -- those nuances effectively to evaluate the
22 information that exists.

23 And the other thing that this group does,
24 particularly for a drug that is in fairly late stage
25 where there are a lot of data, is they look at those

1 data and they particularly look at the correspondence,
2 all the correspondence that has gone on between the
3 Food and Drug Administration and the company, because,
4 for instance, you don't get to Phase III clinical
5 trials with a pharmaceutical product without having had
6 a fair number of interactions with the FDA, and you
7 want to know what questions the FDA has raised and
8 whether those questions have been answered, or indeed,
9 whether those questions are even answerable. And so it
10 involves pretty extensive evaluation of the
11 communication and interaction with the various
12 regulatory authorities.

13 I'm sorry to be carrying on a monologue here if
14 that's what you --

15 MS. SHORES: Same objection, Your Honor.

16 JUDGE CHAPPELL: Doctor, you need to listen to
17 the question and answer only the question that's asked.

18 THE WITNESS: I'm sorry.

19 JUDGE CHAPPELL: Proceed.

20 BY MR. SILBER:

21 Q. In doing the regulatory affairs review, you had
22 talked about site visits before on other issues.

23 A. Yes.

24 Q. Are there site visits done as part of
25 regulatory review?

1 A. Yes.

2 Q. And what type of documentation is reviewed in
3 such a site visit?

4 A. What I just said, you know, that they -- the
5 interactions -- internal memos dealing with regulatory
6 issues and external memos between the regulatory
7 authorities and the various people within the company.

8 Q. And what kind of training do people in
9 regulatory affairs have to have the kind of expertise
10 to review these documents?

11 A. They typically come from one of two corners,
12 sometimes both. In the old days particularly, these
13 fellows often had legal training. Now I think there's
14 a little bit more of a movement for them to have
15 scientific training, that is, to have come out of the
16 R&D departments, but generally there's a mixed bag of
17 them where each major regulatory department has people
18 that have experience in -- they come at it from the
19 legal side and from the scientific side.

20 Q. Okay. Moving on to the next box, intellectual
21 property, let's just start by identifying the types of
22 issues that are reviewed in an intellectual property
23 review.

24 A. Yes, well, for instance, up here it will have
25 been ascertained whether there are patents issued,

1 whether there are patent applications, and that's about
2 it.

3 Down here, the question really becomes how good
4 are those applications, how good are those issued
5 patents? And so in-house patent counsel, sometimes
6 with the assistance of outside people, look at, again,
7 what I think is referred to as the file wrapper; that
8 is, you know, the full documentation of the prosecution
9 history of a patent.

10 Q. Let's move along to the last box there,
11 commercial assessment. Describe for us what issues are
12 evaluated in a commercial assessment.

13 A. Well, this is again a -- these are typically
14 people from the marketing area, and these are typically
15 the people who are going to have the obligation and
16 responsibility to sell the drug. You know, this fellow
17 will have done a commercial assessment, but then he's
18 going to walk away. He's not going to have to sell --

19 Q. When you say "this fellow," the preliminary
20 evaluation box?

21 A. I'm sorry, yes, the people -- the licensing
22 department people typically are also not the people who
23 are having to have responsibility to sell as well, and
24 so the people here in commercial assessment, the
25 marketing people, are going to have that

1 responsibility, and so they not only have the
2 experience, but they have the responsibility to
3 generate these numbers and to generate the financial
4 potential of the various products, and there's often an
5 interesting little interaction between these people and
6 these people (indicating), because these people often
7 have an incentive to keep those numbers as low as
8 possible, because they are going to have to meet those
9 numbers if the drug is actually licensed, and so
10 there's sometimes a little tension where the champion
11 up here, the quarterback, if you will, wants this to be
12 bigger than these guys are willing to buy.

13 Q. Okay. We've got --

14 MS. SHORES: I would object to that last answer
15 as nonresponsive to the question. I think the first
16 part of it might have been responsive, but I think Dr.
17 Levy strayed off into different territories.

18 JUDGE CHAPPELL: I am going to overrule that
19 objection. I sustained your previous one regarding the
20 narrative, and you're right, Ms. Shores, that it wasn't
21 responsive to the interjected question by the complaint
22 counsel, which was, "When you say 'this fellow,' the
23 preliminary evaluation box," but I think it was
24 responsive to the pending question which hadn't been
25 answered properly, so I am going to overrule the

1 objection, but I have sustained two objections for
2 narrative, and again, I advise you to listen to the
3 question and only answer the question that's asked,
4 sir.

5 THE WITNESS: I'm sorry, sir, I'm just not
6 accustomed to this.

7 JUDGE CHAPPELL: You may proceed.

8 MR. SILBER: Thank you, Your Honor.

9 BY MR. SILBER:

10 Q. Okay, let's move on to the manufacturing
11 assessment box, and tell us what type of issues are
12 analyzed there.

13 A. I'm trying to --

14 Q. Yeah, just focus on the type of issues.

15 A. Yes, the type of issues are whether the drug
16 can be manufactured and by whom.

17 Q. Okay. And to make a determination on those
18 issues, what does a licensee do to evaluate those
19 issues?

20 A. That depends on whether or not the licensee
21 intends to manufacture the drug itself or whether the
22 licensee intends to have the drug manufactured by the
23 licensor, or thirdly, whether the intent is to have the
24 drug manufactured by an independent third party.

25 Q. Okay. If you could elaborate on those three

1 things.

2 A. Okay, if the drug is going to be manufactured
3 in-house, then the question is will the -- will the
4 existent manufacturing capability of the company be
5 sufficient to make this particular drug, or will there
6 need to be, for instance, a new plant built to make
7 this drug? And if so, then it goes back up to
8 financial analysis, because obviously a plant would
9 have to be built.

10 If it's going to be manufactured by the
11 licensor, then it becomes very important to determine
12 whether, indeed, the licensor is capable of
13 manufacturing the drug, capable of manufacturing the
14 drug to the quality that will be required by the
15 regulatory authorities and in the volumes that are
16 going to be needed to fill the commercial assessment,
17 the marketing projections, that the marketing people
18 have come forth with.

19 And if it's going to be manufactured by a third
20 party, then one has to -- has to ask, well, what is the
21 cost going to be? How stable is this third-party
22 manufacturer? You know, does this third-party
23 manufacturer have the ability, reputation and so on to
24 make the drug under what we call CGMP, that is good
25 manufacturing practices?

1 And so particularly for the second two, this
2 would involve an audit where various experts from
3 the -- from the manufacturing department of the
4 potential licensee will actually visit the site and
5 look very carefully at the answers to those questions.

6 Q. Okay. Now, over to the right from
7 manufacturing assessment, you have down the side listed
8 deal negotiation. Can you just start by telling us why
9 you placed that box in that way on this slide?

10 A. Yes, because they'll -- again, one has this
11 quarterback here who has been following this process as
12 it ensues, and when it looks like it's doing pretty
13 well getting through all this, he wants to get a
14 running start on it. He doesn't want to wait until
15 everything is done. And so he will typically start
16 real significant negotiations with the licensor at
17 around this point. Things are looking good. Let's get
18 started. Let's start talking.

19 Q. At this point, when they start talking, what
20 type of issues come up? What type of things are they
21 discussing at this stage?

22 A. Well, there are myriad issues, you know, I mean
23 ironically, the deal terms, you know, the financial
24 terms that we spoke of earlier are -- I mean, are
25 brought up, but they're only one, sometimes even minor

1 issues.

2 For instance, a major issue that almost always
3 comes up deals with the assiduousness of each party.
4 The licensor is usually concerned that the licensee
5 will develop and market the product aggressively and
6 effectively. The licensee is concerned that the
7 licensor will finish the development or will, you know,
8 provide certain data and the like. And so there are a
9 lot of, if you will, performance elements that go into
10 these agreements.

11 There are a number of -- a lot of debate often
12 goes on about who shall own the patents and who shall
13 be responsible for the -- for infringements should they
14 arise. I don't want to belabor this point unless you
15 would like me to, but there are a multitude of issues
16 that get discussed in any of these license
17 negotiations, depending on the deal and on the
18 individual elements of the deal in addition to the
19 financial terms, which, of course, are discussed, as
20 well as the territory, you know, that the license will
21 cover.

22 Q. Okay. At this point, have we gotten through
23 the evaluation process?

24 A. Well, as -- here you haven't. I mean, this is
25 the -- the negotiations are going on --

1 Q. Let me phrase the question a little more
2 clearly.

3 A. Okay.

4 Q. Once you get through deal negotiation, are you
5 generally through the evaluation process?

6 A. No, then you have two -- well, in
7 Schering-Plough you have two, in some companies you
8 have a little more than that, in some companies you
9 have less than that, you still have -- after you're
10 done with coming to the conclusion that you want the
11 drug and that you've negotiated a deal that seems to be
12 acceptable to the parties, now you have to put it
13 through the top management of the company, and this
14 will involve presenting the deal in the instance of the
15 current situation to -- it sounded like to this group
16 which was called the PRB, which is a large group of --
17 or a relatively small group, actually, of the most
18 senior people in the company.

19 And seeing that deal then went, as they pass
20 through that, to the SPOC, or the Schering-Plough
21 Operating Committee, and if it got past that, if the
22 deal were large enough, I presume, I guess they didn't
23 take all their small deals, but any deal of any
24 substance, and I don't know what the cut-off point was
25 at Schering-Plough, it also had to be approved by the

1 board of directors, at least, or the executive
2 committee of the board of directors.

3 When I was at Abbott, anything over \$3 million,
4 I think it was, had to go to the executive committee of
5 the board. Anything over \$5 million had to go to the
6 board. But that was a while ago, so I presume those
7 numbers might be a little bit higher now.

8 Q. In your experience in the pharmaceutical
9 industry, have you sat on these entities for which
10 approval is necessary before a licensing deal is
11 completed?

12 A. Yes, I have.

13 Q. Can you give us a few examples?

14 A. Well, at Abbott I was on the Pharmaceutical
15 Operating Committee, and so any deal that had to be --
16 that was going to be licensed at Abbott went through
17 that, and they didn't have the -- at Abbott, the
18 structure was a little different, so I actually had it
19 twice, because I was on the Commercial -- the
20 Commercial Development Committee -- Business
21 Development Committee, I mean, as well as the
22 Pharmaceutical Operating Committee. So, I got a double
23 dose of it.

24 And then when I've been on a board of
25 directors, of course, you know, that has always been

1 the final approval for these -- for these drugs. And
2 then also at Fujisawa, you know, I actually chaired the
3 Pharmaceutical Operating Committee.

4 Q. So, we've now gotten through the whole
5 evaluation, gotten through the negotiation, gotten
6 through the approval, and then at the bottom, you have
7 "deal execution." What does "deal execution" mean?

8 A. Sign the deal.

9 Q. And is that a significant event for a
10 pharmaceutical company?

11 A. Yes, it's a -- we usually have a party. I
12 mean, it's been a long --

13 JUDGE CHAPPELL: Excuse me, Doctor. Would you
14 read the question back, please, Reporter.

15 (The record was read as follows:)

16 "QUESTION: And is that a significant event for
17 a pharmaceutical company?"

18 JUDGE CHAPPELL: See, I believe that's a yes or
19 no answer, Doctor. You're anticipating what's to come,
20 but you can't do that, okay?

21 THE WITNESS: Okay, I'm sorry.

22 Yes.

23 BY MR. SILBER:

24 Q. Okay. And why is that a significant event?

25 A. It just doesn't happen very often. You know,

1 it's a -- we're excited because we have the prospect of
2 a new product, and, you know, new pharmaceutical
3 products are -- unfortunately don't happen to us every
4 day.

5 Q. Okay. Now, again, how long does this whole
6 process take from preliminary evaluation through deal
7 execution?

8 A. Here I showed it to be approximately six
9 months. In my own experience, it's actually usually
10 been a bit longer than that, but I'd say the range has
11 been from about four months to two and a half years I
12 think I've endured one.

13 Q. And through this whole process in general, how
14 many people are involved in the whole due diligence
15 process?

16 A. If it gets all the way through the process?

17 Q. Yes, and to be clear, also, from the licensee
18 side.

19 A. Oh, dozens.

20 Q. Okay, would you have a seat, please.

21 A. Thanks.

22 Q. I think I actually asked you to sit down too
23 soon.

24 A. That's okay.

25 Q. Let me ask you a couple questions first.

1 Have you had the opportunity to examine the due
2 diligence that Schering conducted in looking at
3 Niacor-SR?

4 A. Yes, I did.

5 Q. And can you describe for us what Schering did
6 in evaluating Niacor-SR?

7 A. Well, I think that's on another graphic, so I
8 see why you want me to get back up again, if I may.

9 Q. That slide, Your Honor, is CX 1607 labeled
10 Niacor-SR Licensing Evaluation Process, and with your
11 permission, Dr. Levy can illustrate again.

12 JUDGE CHAPPELL: Yes, he may.

13 MR. SILBER: Thank you.

14 BY MR. SILBER:

15 Q. Dr. Levy, starting with this slide, if you
16 could start with the preliminary evaluation and tell us
17 what was done.

18 A. Tell you what was done?

19 Q. Well, let me back up.

20 If you could just start in general and describe
21 for us the evaluation that Schering did in looking at
22 Niacor-SR.

23 A. As far as I can see, they had what I would
24 perceive as a preliminary evaluation package, you know,
25 20 or 30 pages of -- or maybe less even of information

1 on the product, and they had a single individual, Mr.
2 James Audibert, evaluate it, and to my knowledge, he
3 made no visits to Upsher-Smith, and so I would say that
4 he got, following this slide, about a third of the way
5 through the preliminary evaluation.

6 Q. What happened after he got a third of the way
7 through the preliminary evaluation? And if we could
8 have the next graphic.

9 A. Well, what happened, he -- he wrote up a
10 summary and the deal got executed.

11 Q. So, it went in your opinion from preliminary
12 evaluation directly to deal execution?

13 A. It seemed that way. He discussed it -- I mean,
14 all of this information is coming from my having read
15 his and a few other depositions. The whole process
16 took five days, and -- oh, yes, that's shown here now.
17 In a five-day period, it went from signing the CDA on I
18 guess it was June 12th and signing the deal on June
19 17th, and I think during this period here where I've
20 put a question mark, because I really don't know what
21 they did, I know that from his testimony and from Mr.
22 Lauda's testimony that the two of them conferred, and I
23 think there was some conferring as well with Mr. Kapur
24 and perhaps even with Mr. Wasserstein, but that's all I
25 know of, and then it was -- it was submitted, you know,

1 to be signed. The deal was signed.

2 Q. Based upon your review of the evidence -- and
3 let me just back up a step.

4 What have you reviewed regarding the
5 evaluation? What type of documentation?

6 A. I reviewed the exhibit to Mr. Audibert's
7 deposition which I believe he testified to as being the
8 information in total that he was provided by
9 Upsher-Smith and upon which he relied in making his
10 evaluation.

11 Q. And based upon your review of the evidence, was
12 there any research and development review as you had
13 described before?

14 A. None whatsoever.

15 Q. Paula, if you could place an X there.

16 And was there any financial review, as you had
17 described before?

18 A. None whatsoever.

19 Q. If we could have an X there.

20 And was there any regulatory review as you had
21 described before?

22 A. No, there was no conferring at all that I could
23 ascertain with anybody in regulatory affairs.

24 Q. If we could have an X there.

25 And was there any intellectual property review

1 or commercial assessment?

2 A. As far as I could see, he conferred with no one
3 with patent -- who was a patent lawyer of any type.

4 Q. Okay, if we could have an X under intellectual
5 property, and I had also asked if there was any
6 commercial assessment.

7 A. Again, none of the individuals with the
8 responsibility for marketing this product in the
9 European Union were consulted.

10 Q. Okay, if we could have an X there.

11 And finally, based upon your review of the
12 assessment, was there any manufacturing assessment
13 here?

14 A. None that I could see.

15 Q. So, based upon your review of the evidence, the
16 process here went straight from preliminary evaluation
17 to deal execution, skipping all the other steps in
18 between that you identified?

19 A. As far as I could see, all the evaluation was
20 done by a single individual. So, the answer is yes.

21 Q. Okay, now if you could return to your seat,
22 please.

23 Your Honor, if I may, I'd like to provide Dr.
24 Levy with some documentation to review?

25 JUDGE CHAPPELL: Exhibits or --

1 MR. SILBER: Yes, they are, Your Honor, they
2 are exhibits that are admitted.

3 JUDGE CHAPPELL: You may.

4 MR. SILBER: And if I may, I would like to
5 provide one to you, Your Honor, and to opposing
6 counsel.

7 JUDGE CHAPPELL: Okay.

8 BY MR. SILBER:

9 Q. Dr. Levy, in the Redwell that I have provided
10 you, there are kind of two sets of documents that I
11 think are separated by clips or rubberbands, and I'd
12 like you to first look at the first set of documents,
13 and the first document there is CX 1042, and if you
14 could tell us what that document is.

15 JUDGE CHAPPELL: Mr. Silber, you need to take
16 your exhibit off the screen if you're through with it.

17 MR. SILBER: Okay.

18 THE WITNESS: Yes, this was the exhibit to Mr.
19 Audibert's deposition, and I believe it was the same
20 exhibit to several other of the depositions I reviewed,
21 and it represents the totality of the information that
22 was provided by Upsher-Smith to Schering-Plough for Mr.
23 Audibert's review and was the basis of his review or
24 was the sole basis of his review.

25 BY MR. SILBER:

1 Q. Okay. And if we could turn next to CX 1043,
2 and if you could tell us what that document is.

3 A. Yes, this is what we refer to as the protocol
4 for -- or it's actually a draft protocol for a proposed
5 clinical trial that was never performed, but it was the
6 draft of a protocol that would possibly have been
7 carried forth for treating -- for studying Niacor-SR.

8 Q. Okay. And let's look at the next document,
9 which is CX 714, if you could tell us what that
10 document is.

11 A. Yes, this was the same sort of thing. This
12 was -- this was pretty brief, so this wouldn't have
13 been a protocol itself. This would have been a
14 protocol or the, if you will, the front page or so of a
15 protocol for a study also that wasn't ever performed
16 that studied the combination or the use of Niacor-SR in
17 combination with a statin, fluvastatin.

18 Q. Now, these three exhibits, CX 1042, CX 1043 and
19 CX 714, is it your understanding based upon your review
20 of the evidence that this is the totality of the
21 information Mr. Audibert had at the time he evaluated
22 Niacor-SR?

23 A. Yes, it is.

24 Q. Okay. And do you recall when Mr. Audibert
25 received this documentation?

1 A. I believe it was June 12th of 1997.

2 Q. Okay. And do you know what day Mr. Audibert
3 completed his evaluation?

4 A. I don't recall what day. The other -- the next
5 day that I recall is the day that the deal was signed,
6 which I believe was June 17th or 18th of 1997.

7 Q. Okay. And is it based upon those dates that
8 you reached the conclusion that the evaluation took
9 approximately five days?

10 A. Yes, sir.

11 Q. Okay. If we can move on to CX 1044, and if you
12 can tell us the date of this document to start.

13 A. June 17th, 1997.

14 Q. And what is this document?

15 A. This is a document from Mr. Audibert's boss,
16 Mr. Lauda, to a Mr. Ray Kapur, who was, if I'm not
17 mistaken, the president of Warrick Pharmaceuticals,
18 which was the domestic generic pharmaceutical division
19 of Schering-Plough.

20 Q. And contained behind the cover page, what is
21 that document, or the remainder of the document?

22 A. I think this was the summary that I believe was
23 written by Mr. Audibert summarizing the Niacor-SR
24 opportunity.

25 Q. So, this is summarizing the first three

1 exhibits we have gone through earlier, the information
2 that Schering was provided by Upsher?

3 A. Yes. It also contains Mr. Audibert's
4 description of the general area, the general area of
5 hypolipidemic drugs.

6 Q. Okay, let's turn to the next exhibit, which is
7 CX 1386, and if you can tell us what this document is.

8 A. Yes, this was a memo from Mr. Audibert to Mr.
9 Kapur, and it presented Mr. Audibert's what I would say
10 were very preliminary sort of ballpark financial
11 projections and profit projections on this product.

12 Q. Okay. And what is the date of this document?

13 A. June 17th, 1997.

14 Q. Okay. The next document is CX 347. Can you
15 tell us what this document is?

16 A. Yes, sir.

17 Q. What is it?

18 A. This was the agreement that was executed
19 between the parties to license Niacor-SR --

20 Q. Okay.

21 A. -- and the other products.

22 Q. And the final document in this package is
23 CX 341, and if you can tell us what this document is,
24 it really starts on the second page at SP 1200245.

25 A. Yes, this was the presentation that was made on

1 Niacor-SR or this was the -- the information I presume
2 that was provided to the board of directors in
3 preparation for the presentation regarding the
4 Upsher-Smith license to the board of directors.

5 Q. Now, the documentation that we have just gone
6 through that was in this Redwell, based upon your
7 review of the evidence, does this comprise the
8 documentation for Schering's evaluation starting from
9 when it began looking at this drug through to when it
10 executed the deal?

11 A. Yes, I believe it does.

12 Q. And approximately how thick is that
13 documentation?

14 A. About an inch, three-quarters of an inch.

15 Q. Okay. And approximately how many days did the
16 process take for Mr. Audibert to evaluate this product?

17 A. Five days.

18 Q. And how does that time frame compare to what
19 you generally see in the pharmaceutical industry?

20 A. Well, as I said, my experience is, you know,
21 four months to two years or more even, so it's much,
22 much shorter.

23 Q. And based upon your review of the documents
24 concerning Schering's evaluation of Niacor-SR,
25 approximately how many people were involved in the

1 evaluation of Niacor-SR?

2 A. One.

3 Q. And who was that?

4 A. That was Mr. Audibert.

5 Q. And based upon your experience in the
6 pharmaceutical industry, approximately how many people
7 are generally involved in reviewing or evaluating a
8 product for licensing?

9 A. If it goes through the full evaluation process
10 you mean?

11 Q. Yes.

12 A. Dozens.

13 Q. Now, when we started this section of your
14 testimony, the second point of the subopinions towards
15 your ultimate opinion that the \$60 million payment was
16 not for Niacor, your statement said that the due
17 diligence was strikingly superficial. Is that based
18 upon a comparison of the due diligence for the Niacor
19 deal to due diligence for other Schering deals?

20 A. It's based on two things. It's based on,
21 first, my own experience, for instance, as I testified
22 earlier, for instance, when we do a deal at a company
23 much, much smaller than Schering-Plough, First Horizon
24 Pharmaceutical, which does similar deals, these late
25 stage deals, we have a relatively small staff, but the

1 team that is assembled by the company has usually about
2 30 people on it, in-house people and then various and
3 sundry consultants and the like, such as myself.

4 In the course of doing this evaluation, I
5 suggested that just as a frame of reference we try to
6 look at the due diligence that Schering conducted for
7 other pharmaceutical products that it had licensed in
8 roughly the same time -- during roughly the same period
9 in time.

10 Q. Okay. How did you decide what other deals you
11 wanted to look at?

12 A. I tried to look through that, if you will, that
13 list of 33 that I mentioned earlier and tried to pick
14 out some that were, you know, potentially analogous,
15 analogous in that they were pharmaceuticals as opposed
16 to, say, an R&D deal or a diagnostic or something;
17 secondly, occurred roughly around the same time; and
18 where the product to be licensed was another late stage
19 product.

20 Q. Okay. And did you identify any such deals?

21 A. Yes, there were several, one that I knew very,
22 very well from my having been on the Zonagen board and
23 then ironically had enormous similarities qualitatively
24 to this deal was the deal that Schering-Plough did with
25 Zonagen, and so I suggested that you get the due

1 diligence information on that, because I had never seen
2 that information. The deal was done before I was on
3 the board of directors. So, that was one deal I
4 suggested to you to seek documents regarding.

5 Then there were a few other deals analogously
6 that I suggested to you, but I don't remember all of
7 them, but they were all the same thing, late stage
8 pharmaceuticals.

9 MR. SILBER: At this point, Your Honor, we are
10 going to be going through some in camera materials, and
11 I expect that this may take a half hour to 45 minutes,
12 just to apprise the people who need to step out.

13 JUDGE CHAPPELL: Well, we are not going to
14 break until about 3:30 if that's what you're asking.

15 MR. SILBER: No, I wasn't seeking a break. I
16 was just trying to let them know how long this was
17 going to be.

18 JUDGE CHAPPELL: Okay, at this time I'll have
19 to ask the public to leave the courtroom. We are going
20 to consider some in camera or confidential documents,
21 and would someone outside mind turning over the sign I
22 have that states that we're in an in camera session?
23 I'd appreciate it.

24 (The in camera testimony continued in Volume 7,
25 Part 2, Pages 1492 through 1528, then resumed as

1 follows.)

2 JUDGE CHAPPELL: We will take our midafternoon
3 break. We are in recess -- it's about 3:35. Let's
4 take 15 minutes. We're in recess.

5 (A brief recess was taken.)

6 JUDGE CHAPPELL: Reconvene docket 9297.

7 You may proceed.

8 MR. SILBER: Thank you, Your Honor.

9 BY MR. SILBER:

10 Q. If I could have the slide summarizing Dr.
11 Levy's opinion.

12 Dr. Levy, at this point, we have gotten through
13 your first two opinions as to why the \$60 million
14 payment was not for Niacor-SR. Let's talk about the
15 last one, which says, "Post-deal, neither party showed
16 any serious interest in developing and marketing the
17 drug."

18 Can you tell us in general how you reached this
19 conclusion?

20 A. Yes. I had the opportunity to read from
21 depositions and from various and sundry exhibits and
22 assorted documents that I was made privy to both before
23 I wrote my report and some subsequent to that that
24 addressed the questions of basically what the parties
25 did after they executed this deal, and there are

1 certain things that in my own experience parties
2 typically do upon having executed a pharmaceutical
3 license with each other, and I looked to see whether
4 those various and sundry activities were present in
5 this particular case.

6 Q. Have you prepared a slide that summarizes your
7 experience relative to post-deal conduct?

8 A. Yes, sir.

9 Q. If we could pull up CX 1610, which is labeled
10 Post-Deal Conduct.

11 Your Honor, if we may, if Dr. Levy could
12 approach the board to illustrate these points?

13 JUDGE CHAPPELL: Yes, with the caution that --
14 listen to the question, please, and answer only the
15 question.

16 THE WITNESS: Yes, thank you, sir.

17 JUDGE CHAPPELL: You may.

18 BY MR. SILBER:

19 Q. Okay, Dr. Levy, your first point here uses the
20 term "project team." Tell us what you mean by "project
21 team."

22 A. Well, a project team in this instance refers to
23 a product development team or a project development
24 team, and this is comprised of that group within the
25 company that would have the responsibility for

1 shepherding this drug, this licensed product, through
2 the various regulatory hurdles essentially up to the
3 time when the drug was going to become a marketed
4 product.

5 Q. When would a project team be formed relative to
6 execution of a deal?

7 A. Usually the product or project team is formed
8 as the deal negotiations are ensuing and looks like
9 they're going to result in a deal, certainly no later
10 than four milliseconds after the deal has been signed,
11 but usually before.

12 Q. Why is a project team formed at that time?

13 A. Well, there's a -- we have a considerable sense
14 of urgency in taking our products through the
15 regulatory process. Just anecdotally, it's a number
16 that always stuck in my head from the -- I think my
17 second day, my first job in the pharmaceutical industry
18 at Abbott, where my boss, this guy Kirk Robb, who was
19 the president of the company then, who said, I want you
20 to learn one number, Nelson, \$10,000 a day, because
21 every day a drug is not on the market, it costs Abbott
22 \$10,000.

23 Now, there's been a little inflation since
24 then, that would have been a \$300 million drug, but you
25 can do the math. But anyway, he was just trying to

1 illustrate to me, and I'm just trying to illustrate it
2 here, that there was a real sense of urgency, because
3 we want to get these things on the market as
4 effectively as possible.

5 Q. What kind of people would be on a project team?

6 A. I've listed some of them here, and companies
7 vary and -- drug to drug, company to company, but it
8 always has R&D people on it, it always has regulatory
9 people on it, it always has marketing people on it, and
10 sometimes there's more, but those three certainly.

11 Q. How large are these teams generally?

12 A. Again, that varies company to company, drug to
13 drug and situation to situation, but I would say six to
14 25.

15 Q. And after committing to pay \$60 million for
16 Niacor-SR, how large was Schering's project team?

17 A. I'm not sure they had a project team. I think
18 that the -- Mr. Audibert, as far as I could see, was
19 the project team.

20 Q. So, there was one individual based upon your
21 review of the information that consisted of the project
22 team?

23 A. That's all that I could discern, yes.

24 Q. Let's move on to your next point on the
25 post-deal conduct. It says, "Meetings between

1 Upsher-Smith and Schering-Plough to coordinate
2 development, address problems, share information."

3 Describe what you mean by these meetings.

4 A. Well, you just have a partnership that's been
5 formed. Both parties have an enormous interest in
6 getting this product to market and cooperating with
7 each other to do that, and each -- you know, depending
8 on what the deal is and the different circumstances,
9 but usually each party has something to contribute, be
10 it data, personnel, know-how, experience, and they
11 form -- you know, they meet often, share information.
12 Most particularly, they identify problems and they try
13 to solve their mutual problems.

14 So, for instance, with this deal -- I'm sorry,
15 I don't want to go forward. I'll stop.

16 Q. Do you have any personal experience working
17 with Schering-Plough on coordination after a deal has
18 been signed?

19 A. Yes, I do indirectly. As a board member at
20 Zonagen --

21 MR. CURRAN: Your Honor, I object. The answer
22 is going well beyond the question.

23 JUDGE CHAPPELL: Sustained.

24 BY MR. SILBER:

25 Q. Dr. Levy, can you describe for us the personal

1 experience you had at Zonagen?

2 MR. CURRAN: And now, Your Honor, if I may
3 interject a substantive objection. This is an expert
4 witness testifying as to opinions in various designated
5 areas. It appears now he's moving into fact testimony.

6 MR. SILBER: Your Honor, if I may respond?

7 In their motion in limine, they have raised a
8 variety of issues about Dr. Levy's qualifications
9 arguing that he had no relevant experience in the
10 pharmaceutical industry. Here we're simply trying to
11 illustrate that he has relevant experience, and the
12 fact of the matter is, it is with one of the parties,
13 and it does appear to be relevant to this general point
14 as to whether the post-deal conduct between the parties
15 here is consistent with his experience in the industry.

16 JUDGE CHAPPELL: So, your question is going to
17 his experience in this area?

18 MR. SILBER: Yes, it is, Your Honor.

19 JUDGE CHAPPELL: Not to substantive facts
20 regarding this particular agreement at issue here?

21 MR. SILBER: He is to some extent describing
22 his involvement in this to illustrate the point of his
23 experience in the industry. I mean, if they don't want
24 him to testify about this deal, I'm sure Dr. Levy has
25 an example from some other deal that doesn't relate to

1 Schering that could illustrate this point. We would be
2 happy to go into that.

3 JUDGE CHAPPELL: Let me try this again. You're
4 asking the question to qualify the expert --

5 MR. SILBER: I'm -- well, I feel as though
6 we've qualified the expert already. I was kind of
7 raising it in the context of their prior objection to
8 his qualifications that he didn't have industry
9 experience, and I find it kind of ironic that they are
10 now objecting to the fact that he's speaking to
11 specific industry experience that appears to be quite
12 relevant.

13 JUDGE CHAPPELL: Mr. Curran, how is this
14 question going to go into facts?

15 MR. CURRAN: Well, Your Honor, if this subject
16 really dealt with his qualifications, it would have
17 come before lunch today during the section where his
18 qualifications were going forward. The timing of the
19 testimony right now in conjunction with point two on
20 this chart confirms unambiguously that this is not
21 going to his qualifications but, in fact, is fact
22 testimony purporting to support a conclusion that he's
23 advancing in this particular matter.

24 JUDGE CHAPPELL: And tell me again why you're
25 offering this information.

1 MR. SILBER: I'm offering this information
2 because I feel it's relevant to illustrate the point
3 that Dr. Levy is trying to make here as to what
4 normally goes on in the industry after a deal is
5 signed. The second point here talks about coordination
6 between parties, and he has relevant industry
7 experience. It happens to involve a deal involving
8 these parties, but, I mean, he's testified earlier
9 today regarding experiences with other companies,
10 pointing out -- to illustrate other points. I think
11 that's all he's doing here.

12 JUDGE CHAPPELL: Well, Mr. Curran, I am going
13 to overrule the objection. He's still on direct, and
14 we're not on redirect or rebuttal, and so they have the
15 right to ask the question whenever they want to. I
16 understand he's standing up at the chart right now, so
17 I'll keep that in mind, but it's overruled.

18 You may proceed.

19 MR. CURRAN: Thank you, Your Honor.

20 MR. SILBER: Thank you, Your Honor.

21 BY MR. SILBER:

22 Q. Dr. Levy, can you explain to us how your
23 involvement in the post-deal conduct on the
24 Schering-Zonagen deal illustrates your second point?

25 A. Yes, sir. As I said, I was not involved with

1 Zonagen when this deal was executed, but, of course, I
2 know about it, but I was very much involved during the
3 period that, in fact, is still ensuing in terms of
4 getting Vasomax through the FDA.

5 And the reason I raised this particular issue
6 was it shows how these parties, really how any parties,
7 act together to solve problems post-deal, and the
8 interaction between -- a problem arose in the
9 development of Vasomax that was unforeseen by either of
10 the parties, and it's been -- it was a wonderful
11 experience from the Zonagen board perspective to see
12 how cooperative Schering-Plough was in working with us
13 to solve this problem. I mean, they really functioned
14 with us as a partner to get over the regulatory hurdle
15 that we had to overcome.

16 And this is the sort of thing that's typical.
17 I mean, I've seen this, as I said, and I chose this
18 example because it was so relevant to everything I've
19 spoken about. There's virtually every other
20 situation -- absolutely every other situation that I've
21 been involved with with this type of situation where
22 there was a license between two parties, there was
23 fluent cooperation between the two parties to get the
24 drug approved.

25 Q. How does that experience and other experience

1 you have in general on this kind of post-deal
2 coordination, how does that compare with what you saw
3 between Schering and Upsher post-deal for Niacor?

4 A. Well, it was just surprising to me. There's
5 one specific example that just so illustrates the point
6 very clearly, is Upsher-Smith is a small generic
7 pharmaceutical company without a great deal of
8 experience developing branded pharmaceutical products,
9 and from reading their -- the documents of their own
10 internal project team meetings, they had been having a
11 problem for some many months with an integral type of
12 test called a pharmacokinetic study, and there had been
13 considerable interaction between Upsher-Smith and the
14 FDA with the FDA basically saying to Upsher-Smith they
15 weren't going to approve the drug unless they got the
16 pharmacokinetic studies right, and Upsher-Smith seemed
17 to be having considerable difficulty getting their
18 outside contractors, because they didn't have the
19 in-house expertise, to get the outside contractors to
20 perform these pharmacokinetic studies effectively for
21 them.

22 Doing a pharmacokinetic study in
23 Schering-Plough is like falling off a log. I mean,
24 they do them routinely. This is something that they
25 easily, easily, easily could have solved for

1 Upsher-Smith had Upsher-Smith asked them, which as far
2 as I could see they never did, and as far as I know to
3 this day they have not completed the pharmacokinetic
4 studies. So, that's just one example of what easily
5 could have happened, I looked for, and was amazed when
6 I didn't find.

7 Q. Dr. Levy, this point begins with the word
8 "meetings."

9 A. Yes.

10 Q. Based upon your review of the evidence, were
11 there any meetings between Schering and Upsher-Smith
12 post-deal to coordinate on such efforts?

13 A. Not to my knowledge, no meetings whatsoever.

14 Q. And to back up a step, are you aware of any
15 communication between the parties in this period of
16 time post-deal?

17 A. Yes, sir.

18 Q. And can you describe that level of
19 communication?

20 A. Yes, there were a number of memos, usually
21 between Mr. Kapur and some individuals, I believe Mr.
22 Troup at Upsher-Smith and also I think some meeting --
23 some memos from Mr. Audibert to people whose names I've
24 forgotten at Upsher-Smith, requesting various
25 documents.

1 For instance, one thing that they were
2 requesting was, if I remember correctly, the second
3 Phase III clinical trial that Upsher-Smith said it
4 completed had not yet been finalized. They had not
5 done the final report on this second Phase III pivotal
6 trial, and it was supposed to be available in July of
7 1997, the deal having been executed in June of that
8 year. And I guess it was about September or so, there
9 was a memo from Mr. Audibert to someone at Upsher-Smith
10 asking for this report, and as far as I could see, the
11 report was never forthcoming.

12 Q. How does the degree of communication between
13 the parties in these first few months after the deal,
14 how does that compare to what you would generally
15 expect to see post-deal in the pharmaceutical industry?

16 A. It's just -- it's -- to say I was surprised is
17 an understatement. I mean, I've just never seen that.

18 Q. Let's move on to your third point. It's,
19 "Protocols written for EU clinical studies."

20 What does that mean?

21 A. Yeah, this is a -- this is not a general point.
22 This is a specific point relevant to this deal.
23 Schering-Plough had a very, very aggressive product
24 development schedule that they had outlined. Remember
25 that the schedule called for Upsher-Smith to file its

1 new drug application in the United States in December
2 of 1997. Schering-Plough was then going to take that,
3 and then it was going to have to supplement that with
4 some clinical information derived in the European
5 Union, because the European Union doesn't just
6 rubber-stamp FDA approvals, they require some limited
7 clinical trials to be done in their own jurisdictions.

8 And the schedule that Schering-Plough was on
9 was to get approval, not just to file this document,
10 but to get approval of Niacor-SR by the end of 1998.
11 That is but one -- but one year after Upsher-Smith had
12 planned to and said it was going to file its NDA. This
13 is a very, very, very aggressive time frame, because
14 the clinical trials that would have been required in
15 Europe would have taken several months, maybe six
16 months, maybe a little bit less if they were really
17 aggressive, but they were not trivial, and then
18 collecting those data, analyzing those data, processing
19 those data, putting it all together in the -- in the
20 format requisite to file the document in the European
21 Union, and then wait for review of that document in the
22 European Union, which itself would have taken several
23 months, and then to try to meet a timetable for
24 approval at the end of 1998 was very, very aggressive.

25 And so what they would have had to do was to

1 have a real running start on this process, and a
2 running start would have been certainly to have the
3 regulatory input and the clinical protocols written so
4 that from the moment that deal was executed, they are
5 getting those clinical trials going in the EU, because
6 otherwise, there was no way that they could meet that
7 time frame, and I saw no evidence whatsoever that any
8 of these protocols were written.

9 Q. Let's hit your last point. "Full disclosure by
10 Upsher-Smith to Schering-Plough regarding development
11 problems and change."

12 What types of development problems and change
13 are you speaking to?

14 A. I was fortunate to be able to see some -- at
15 the time I wrote my report, some brief documents that
16 were brief meeting minutes from what looked like
17 Upsher-Smith's internal project team meeting.
18 Subsequent to that, we've seen more detailed minutes of
19 those meetings that's enlarged upon that, but this
20 group met essentially every month, and the deal was
21 executed in June.

22 In October -- well, they were having trouble
23 with this pharmacokinetic study that I mentioned
24 before, and this was alluded to in the previous project
25 team meetings, but just jumping ahead, in the minutes

1 from a meeting held in October, just a few months after
2 the deal was executed, a very dramatic issue was
3 raised, and that's that it was proposed that
4 Upsher-Smith slow down, essentially stop, its
5 development of Niacor-SR as an NDA drug, that is, as a
6 branded drug, and instead that the company embark upon
7 and devise what they referred to as an ANDA strategy.
8 That stands for abbreviated new drug application,
9 strategy.

10 Now --

11 Q. Dr. Levy, by looking at these minutes, you
12 indicated that this change was reflected in October of
13 1997?

14 A. Yes, sir.

15 Q. Is that correct?

16 And why would this change in strategy by
17 Upsher -- or let me say, would this change in strategy
18 by Upsher be of significance to Schering?

19 A. It would have been utterly an anathema.

20 Q. And why is that?

21 A. An ANDA or an abbreviated new drug application,
22 as its name implies, is an abbreviated application. It
23 is used by generic pharmaceutical companies to file for
24 a -- essentially their duplicate of another product, a
25 generic product, and so they were presumably going to

1 file this ANDA as a generic substitute for Niaspan that
2 had been approved in July.

3 So, here is Schering-Plough, a branded
4 pharmaceutical company largely, who is expecting to
5 register and market Niacor-SR as a branded
6 pharmaceutical product and depend for this filing upon
7 a new drug application, a full NDA, that was going to
8 be filed by Upsher-Smith. Upsher-Smith was changing
9 this strategy, and as far as I could see did so without
10 any notification of Schering whatsoever.

11 Q. Did Upsher at some point tell Schering about
12 its change in strategy on Niacor?

13 A. Yes, as I read the minutes, they started
14 discussing this in October of 1997, and they agreed to
15 do it in November of 1997 --

16 Q. I'm sorry, when you say "they agreed to do
17 it" --

18 A. Internally -- not they, Upsher-Smith internally
19 decided to do it. In January of 1998, their memo said
20 they have put the NDA on hold, and the earliest that
21 Schering-Plough was notified was September of 1998,
22 almost a year after they made that decision. That's
23 inconceivable to me.

24 Q. Would you sit down.

25 Can we have the slide summarizing Dr. Levy's

1 opinion again.

2 Dr. Levy, in reaching your ultimate conclusion
3 that the \$60 million noncontingent payment was not for
4 Niacor, aren't you simply second-guessing what the
5 Schering business people -- second-guessing their
6 business judgment and imposing your own opinion on the
7 deal?

8 A. I don't think so, sir.

9 Q. Would you elaborate?

10 A. I'm sorry.

11 I think each of these three points is -- you
12 know, is based upon facts, not my opinion. For
13 instance, the \$60 million payment is what it is. It's
14 \$60 million. It is much larger than any payment that
15 Schering-Plough ever made. It's not my opinion; that's
16 a fact. It's also larger than I personally had ever
17 seen, I think anybody had ever seen, for an analogous
18 payment up to that time for any pharmaceutical. So, I
19 mean, it was -- it was very large for a drug that
20 nobody has said was a major drug. So, that's not -- I
21 mean, that's not an opinion. I believe it's a fact.

22 In terms of the due diligence, yes, it's my
23 opinion that it would be strikingly superficial, but I
24 think the thing spoke for itself. They had one person
25 working for five days compared to their own company

1 that had 50 people working for seven to nine months on
2 similar deals, and -- and so, again, I don't think that
3 I'm second-guessing them. Those facts speak for
4 themselves.

5 In terms of the last, the behavior was just so
6 inconsistent with anything I've ever seen that I don't
7 think I'm trying to substitute my business judgment.
8 I'm just sort of comparing what I have seen and
9 experienced with what I saw and experienced or saw in
10 this -- in this matter.

11 Q. One last question. To reach your opinion that
12 the \$60 million payment was not for Niacor, you've gone
13 through the three points below it concerning the size
14 of the payment, the due diligence and the post-deal
15 conduct.

16 A. Yes, sir.

17 Q. To conclude that the \$60 million payment was
18 not for Niacor, do you need to rely on all three of
19 those factors?

20 A. No.

21 Q. And why is that?

22 A. I think each one stands on its own merit. Even
23 if one were to assume that the \$60 million was not, you
24 know, out of whack with the typical situation, even if
25 Schering had made some other \$60 million payments

1 analogous to this, even if it wasn't extraordinary in
2 the industry to make that payment, which by nobody's
3 assertion is a small payment, with five days due
4 diligence by one guy, for instance, is -- is, you know,
5 strikingly, you know, dramatic to me.

6 Even had they done due diligence, even had they
7 spent the \$60 million for a drug that had \$60 million
8 worth of value in it, what they did after they had done
9 this deal -- they just paid \$60 million. Let's say
10 they did do seven months due diligence on this thing
11 before they paid the \$60 million. To let life follow
12 for all that period, to do nothing further with it, not
13 to communicate with each other that one party had
14 essentially stopped development, without telling the
15 other for almost a year? That speaks for itself.

16 So, any of those three opinions, if the others
17 weren't even present, would have led to the same
18 conclusion I have at the top.

19 MR. SILBER: Thank you, Dr. Levy. That's all
20 we have, Your Honor.

21 JUDGE CHAPPELL: And I think the parties have
22 agreed that cross examination of this witness will
23 begin on Tuesday morning, February 5th?

24 MR. SILBER: That is correct, Your Honor.

25 MR. CURRAN: That's right, Your Honor, we're

1 going to have to be very patient until then.

2 JUDGE CHAPPELL: Okay, and at this time the --
3 I think the Government needs to call your next witness,
4 and I think that's by deposition transcript --

5 MR. SILBER: I believe so, Your Honor.

6 JUDGE CHAPPELL: -- excerpt? Okay.

7 THE WITNESS: May I -- okay.

8 JUDGE CHAPPELL: Mr. Levy, you're excused for
9 now.

10 THE WITNESS: Thank you, sir.

11 JUDGE CHAPPELL: The fun's just starting, sir.

12 THE WITNESS: I'm afraid of that.

13 JUDGE CHAPPELL: Are we going to adhere to the
14 procedure we used before for deposition excerpt
15 reading?

16 MS. BOKAT: Your Honor, what we were proposing
17 to do, hopefully consistent with the procedure you set
18 out the last time we were doing readings, I would like
19 to call on Ms. Yaa Apori and Mr. Andrew Ginsburg to do
20 the readings on behalf of complaint counsel. What we
21 planned to do would be to have them read from a single
22 witness, for example, an investigational hearing, and
23 then allow respondents to do counter-readings on that
24 same witness.

25 Is that acceptable?

1 JUDGE CHAPPELL: That makes a lot of sense.
2 That's absolutely acceptable.

3 Do the respondents have their
4 counter-designations ready for the witnesses?

5 MS. SHORES: We do, Your Honor.

6 MR. CARNEY: Yes, Your Honor, we do.

7 MS. BOKAT: Now, in terms of timing, Your
8 Honor, we have got, what, about an hour to play with.
9 In fairness, we thought we would start with a witness
10 that's fairly short to allow respondents time today for
11 counter-readings on that witness rather than having us
12 read an hour and have them not have the opportunity
13 today to counter-read.

14 JUDGE CHAPPELL: I think if we don't finish
15 today, we will finish in the morning. We'll wrap up
16 whatever counter-readings we need in the morning.

17 MS. BOKAT: Rather than starting with the
18 witness tomorrow morning?

19 JUDGE CHAPPELL: Are you anticipating three
20 hours of counter-designations by respondent? It was
21 fairly brief the last time we did this.

22 MS. BOKAT: Right. We estimate that our
23 remaining readings would take approximately two hours,
24 not accounting for counter-readings. So, what we would
25 like to do would be to do a reading, keeping the time

1 confined so that the other side could do
2 counter-readings for that person, and then maybe after
3 the witness tomorrow, if we have some more non-witness
4 time, we could take up readings again.

5 Would that be acceptable?

6 JUDGE CHAPPELL: Why don't we see when we get
7 to a stopping point how much you have to go, how much
8 counter-designation we have, and then I'll decide
9 whether we'll do it before or after the witness
10 tomorrow. I understand the witness' constraints that
11 we have coming tomorrow, but with that, let's go ahead.

12 MS. BOKAT: Thank you.

13 (Pause in the proceedings.)

14 MS. BOKAT: Your Honor, Ms. Apori and Mr.
15 Ginsburg are going to begin with excerpts from the
16 investigational hearing transcript of Martin Driscoll.
17 That hearing was conducted July 10th, year 2000. At
18 the time of the conduct in question, Mr. Driscoll was
19 an official of Schering-Plough. I believe at that time
20 he was vice president of sales and marketing within Key
21 Pharmaceuticals.

22 JUDGE CHAPPELL: Thank you. You may proceed.

23 MR. GINSBURG: Thank you, Your Honor.

24 Page 44, line 7:

25 "QUESTION: Does Schering try to get

1 information from the other company, the
2 company that owns the product in order to do
3 this forecast?

4 "ANSWER: Well, generally, if you were in
5 negotiations for the licensing of a product,
6 generally you have secrecy agreements,
7 agreements on confidentiality that have been
8 established, and there's a due diligence that
9 occurs.

10 "QUESTION: What goes on in the due
11 diligence?

12 "ANSWER: Well, importantly one element of
13 due diligence that's essential is if, for
14 example, you're looking to license a product,
15 we want to ensure that the clinical profile is
16 what the other party has stated it is in terms
17 of its safety and efficacy.

18 "Our research people will evaluate it to
19 determine whether the product is safe and
20 effective under our standards, the standards
21 of the federal government or the various
22 regulatory agencies. That's one element of
23 the due diligence."

24 MR. GINSBURG: Page 83, line 23:

25 "QUESTION: Had Kos completed all their

1 clinical work on this product?

2 "ANSWER: They had -- my recollection was
3 they completed all their clinical work that
4 was part of their filings at the Food and Drug
5 Administration. They had filed their
6 application. I believe they were doing
7 additional trials, which is not uncommon.
8 Companies will do additional trials in
9 addition to their package filed with the FDA
10 because they may be seeking down the road
11 additional indications, broader use of the
12 products.

13 "But their pivotal trials that were part of
14 the filing -- in fact, if my memory serves me
15 correctly and I recall correctly, they had
16 already filed their application with the FDA
17 for approval in the United States.

18 "QUESTION: Did Kos have any estimates of
19 what their dollar or prescription sales of
20 this product would be?

21 "ANSWER: Yes.

22 "QUESTION: What were they predicting?

23 "ANSWER: Well, I recall -- and this is
24 based on my memory -- I recall that they
25 seemed to feel that this product was in its

1 second year -- 175 to \$200 million product in
2 the United States, and long-term was an even
3 bigger product, perhaps as high 4 or 500
4 million.

5 "QUESTION: Did Schering-Plough come up
6 with its own estimates of what the sales
7 potential for this product was?

8 "ANSWER: We did.

9 "QUESTION: What were your estimates?

10 "ANSWER: Well, first off, we agreed that
11 the opportunity for a niacin product,
12 sustained release niacin product that met the
13 unmet needs that existed in the marketplace
14 could be big, in excess of a \$500 million
15 product, but after further review of the Kos
16 product, I in particular did not feel that it
17 met those needs and did not -- would not yield
18 the sales potential that Kos felt it would.

19 "QUESTION: What was it about the Kos
20 product that didn't appear to meet the needs?

21 "ANSWER: Two things. First and foremost
22 as I reviewed the clinical information on the
23 product, I felt they had too high a rate of
24 flushing, and I remember -- I remember this
25 number, it's just in my memory, that they had

1 an 88 percent incidence of flushing in their
2 pivotal clinical trial.

3 "Now, I remember their attempt to explain
4 that away was the product was -- you could
5 avoid that by dosing it prior to bedtime, that
6 in effect the flushing would occur while the
7 individual slept. They had the benefits of
8 the niacin, and you wouldn't see flushing
9 during the day when they're out and about.

10 "To me I just fundamentally felt that it
11 still had a high degree of flushing, that it
12 was not overcoming the key need in the
13 marketplace for a niacin product. We were
14 still greatly interested in niacin. We
15 thought that 4 or 500 billion market that I
16 described earlier, that a niacin product that
17 was a sustained release without the flushing
18 would be big in the marketplace.

19 "I didn't feel the Niaspan product yielded
20 that."

21 MR. GINSBURG: Page 89, line 16:

22 "QUESTION: Was it in approximately August
23 of '97 that Kos actually went to market with
24 this product?

25 "ANSWER: That's my recollection.

1 "QUESTION: Did the sales live up to Kos'
2 predictions?

3 "ANSWER: For once I think I was right.
4 It was a major disappointment for them. If I
5 remember correctly, their second year sales
6 totaled \$15 million, and that's just from the
7 best of my recollection. I recall very
8 clearly and -- I may be correct on my dates, I
9 hope I am, I recall in September -- I believe
10 it was September of '97, their first month of
11 prescriptions were very low, very
12 disappointing, and there was a lot of scrutiny
13 about what their performance was going to be
14 thereafter.

15 "QUESTION: When you were having the
16 discussions with Kos, did you ever come up
17 with a dollar figure you were projecting for
18 the potential sales of this product?

19 "ANSWER: For their product?

20 "QUESTION: Yes.

21 "ANSWER: Oh, yes.

22 "QUESTION: And what were your
23 projections?

24 "ANSWER: Mine, my projections were that
25 this product, based on the profile I had

1 seen -- and again based on the information
2 available to me, we had not gone to a heavy
3 due diligence, had not been given the benefit
4 of broad information, but based on what was
5 available to me, my sense of that product and
6 profile was max 60 to \$70 million product one
7 day.

8 "QUESTION: That would be --

9 "ANSWER: Perhaps per year, in perhaps the
10 year three to four so its greatest potential
11 in any given year in my judgment was a 60 to
12 \$70 million.

13 "QUESTION: Has it ever gotten to that
14 point?

15 "ANSWER: No, ma'am. I haven't looked at
16 it in some time now. If it's a \$50 million
17 product in the United States I would be very
18 surprised, but again that's simply a guess."

19 MR. GINSBURG: That's all we have, Your Honor,
20 for Mr. Driscoll's investigational hearing.

21 JUDGE CHAPPELL: Respondents?

22 MS. BIERI: We have some counters, Your Honor.

23 MS. SHORES: We do have some counters, Your
24 Honor, and Ms. Bieri and Mr. Koons will be handling
25 those.

1 JUDGE CHAPPELL: Thank you. You may proceed.

2 MS. BIERI: Starting at page 42, line 14:

3 "QUESTION: In your tenure at
4 Schering-Plough, have you been involved in
5 agreements to license in pharmaceutical
6 products?

7 "ANSWER: Yes.

8 "QUESTION: What has your involvement
9 been?

10 "ANSWER: My involvement principally
11 through my years with Schering-Plough in my
12 various capacities has principally been to
13 forecast the potential commercial performance
14 of the products we're seeking to license and
15 ultimately licensing and to determine the
16 operational issues that will be necessary in
17 commercializing those products.

18 "QUESTION: How do you go about trying to
19 forecast the potential commercial performance
20 of a product that Schering might license in?

21 "ANSWER: Well, first it's very difficult.
22 It's a lot of guesswork. I think the most
23 fundamental measure to utilize, we attempt to
24 use history to gauge the future.

25 "QUESTION: Can you explain what you mean

1 by using history?

2 "ANSWER: We attempt to see the
3 performance of a given market for a product,
4 products. We look at the needs of the
5 marketplace in that given point to the degree
6 that those needs are being satisfied so we can
7 determine the gap in the needs of the
8 marketplace, the product or the products that
9 we're looking at and determine to what degree
10 they meet those needs.

11 "And we attempt to forecast the performance
12 of the products based on the value that
13 they're bringing in to that marketplace versus
14 the needs or gap, the gap in needs that exist,
15 needs gap that exists in the marketplace.

16 "QUESTION: Do you try to predict dollar
17 or prescription sales of the product?

18 "ANSWER: Yes, we attempt to do that. We
19 attempt to predict -- we attempt to forecast
20 it. We guess at it.

21 "QUESTION: Does that analysis differ
22 depending on whether the product has already
23 been approved and is on the market?

24 "ANSWER: I have to say that would just
25 depend on the situation. It varies. Each

1 market is different. Each situation is
2 different. It's one of the tough challenging
3 parts of our job is the dynamics of every
4 market and every product varies so I would
5 have to say it just varies."

6 MS. BIERI: Going to page 45, line 11:

7 "QUESTION: Now, are there things other
8 than the clinical profile that are part of the
9 due diligence?

10 "ANSWER: Again, I must tell you it
11 depends on the situation and whether -- what
12 role we might play in the situation, whether
13 we're simply going to sell the product or
14 whether we're actually going to license it and
15 manufacture it, distribute it versus whether
16 we're simply going to distribute. It just
17 depends on what the particular discussions and
18 negotiations involve."

19 MS. BIERI: Page 45, line -- I'm sorry, page
20 46, line 8:

21 "QUESTION: What I'm trying to do is not
22 focus on any particular agreement but just get
23 a sense of what goes into due diligence, and
24 it sounded like this was sort of hard to
25 answer that broadly, so I was trying to at

1 least slice out some of the complications and
2 first get rid of the situation where Schering
3 might simply be marketing a product but would
4 have more of a role in trying to find out what
5 would have to go on in due diligence.

6 "ANSWER: And I have to answer and tell
7 you that every situation is different. They
8 vary. The scope of a due diligence is
9 dependent on the situation, and it can vary
10 from one to the other."

11 MS. BIERI: Going to page 86, line 8:

12 "QUESTION: Did niacin have a potential to
13 meet a market need that wasn't being met by
14 the other cholesterol-reducing agents such as
15 the statins?

16 "ANSWER: Yes, it did. One of the
17 benefits -- physicians oftentimes over time
18 will have to prescribe more than one
19 cholesterol lowering agent for a person with
20 high cholesterol, and the statins as you
21 described, as you mentioned, are very
22 effective agents but oftentimes they're not
23 effective -- they're not sufficiently
24 effective as monotherapy. In many cases
25 physicians will prescribe a statin plus a

1 niacin, for example.

2 "QUESTION: So, the niacin wouldn't be a
3 replacement for a statin; it would be used as
4 a complementary product?

5 "ANSWER: Yes, yes and yes. In some
6 instances it could be a replacement for
7 various reasons, but for the most part it
8 would be a complementary agent.

9 "QUESTION: Did Schering-Plough Kos get as
10 far as in their discussions talking about what
11 Schering might pay for the license from Kos?

12 "ANSWER: I don't recall that. No, I
13 don't recall that. I ended the discussions.
14 I ended the discussions for two reasons. It
15 became apparent to me that there was a wide
16 gulf between what they saw as the potential
17 for this product in the market and what we
18 saw; and number two, very frankly, their
19 people were treating my people with great
20 disrespect.

21 "And pivotal to any arrangement with a
22 company, a partnership, it's pivotal that the
23 people you're going to work with you know you
24 can get along with and partner appropriately,
25 and that wasn't going to happen in my view, so

1 I ended the discussions."

2 MS. BIERI: That's all for Schering, Your
3 Honor. Thank you.

4 JUDGE CHAPPELL: Thank you.

5 MR. CARNEY: Your Honor, the portions of the
6 excerpts of counter-designations for Upsher are
7 subsumed in what was just read by Schering, so we have
8 nothing to add on this point.

9 JUDGE CHAPPELL: Okay, thank you. Next?

10 MS. BOKAT: Next, Mr. Ginsburg and Ms. Apori
11 will read again from Martin Driscoll, this time from
12 his deposition transcript, and that deposition was
13 taken October 31st, 2001.

14 JUDGE CHAPPELL: Thank you.

15 MR. GINSBURG: Page 72, line 19:

16 "QUESTION: During the time period you
17 were involved in the negotiations with
18 Upsher-Smith, had evaluation of their extended
19 release niacin compound been completed?

20 "MS. SHORES: By whom?

21 "QUESTION: By Schering.

22 "ANSWER: I don't recall that it had. And
23 I don't believe it would have been completed,
24 because I don't recall us getting much
25 information about it beyond just their general

1 description."

2 MR. GINSBURG: Page 74, line 7:

3 "QUESTION: When you were involved in the
4 discussions with Upsher-Smith, did Schering
5 ask for access to Upsher-Smith's files of
6 communications with the FDA about their
7 extended release niacin product?

8 "ANSWER: I don't recall that. I don't
9 recall that.

10 "QUESTION: Do you recall Upsher-Smith
11 providing any documents about their
12 communications with the FDA about their
13 extended release niacin product?

14 "ANSWER: No, I don't recall them ever --
15 I don't recall them providing that.

16 "QUESTION: When you were involved in
17 discussions with Upsher-Smith where they
18 provided any information about any patents
19 they had related to their extended release
20 niacin product?

21 "ANSWER: I never saw nor did I receive
22 any written information. I recall Ian Troup
23 describing that they had some type of a patent
24 that required companies to license whatever
25 was under that patent for the development or

1 marketing of their product that they had been
2 developing, which was Niaspan.

3 "QUESTION: I'm sorry. I got confused.
4 What Mr. Troup was describing, was it an
5 Upsher patent?

6 "ANSWER: Yes, apparently, my recollection
7 was that he was describing the fact that they
8 had a patent position around a niacin
9 sustained release product and, again, I never
10 saw written information of that. We didn't go
11 into more specifics. But I recall that he
12 described that based on that another company
13 that was developing a niacin product, had to
14 take a license from them and pay royalty to
15 Upsher-Smith for the development or the
16 marketing of their product.

17 "QUESTION: Was that other company?

18 "ANSWER: I recall him telling us it was
19 Kos.

20 "QUESTION: Did he inform of you of
21 whether or not companies had the right to
22 sublicense the Upsher-Smith patent?

23 "ANSWER: I don't recall that discussion.

24 "QUESTION: Did Mr. Troup indicate whether
25 Kos had licensed any patents to Upsher-Smith

1 related to the extended release niacin
2 products?

3 "ANSWER: I don't recall that."

4 MR. GINSBURG: Page 84, line 7:

5 "QUESTION: Did Upsher-Smith provide any
6 information to Schering-Plough on the labeling
7 it was seeking for the extended release niacin
8 product?

9 "ANSWER: I don't recall seeing that."

10 MR. GINSBURG: Page 94, line 9:

11 "QUESTION: Do you know whether Schering
12 asked Kos for information on the Niaspan
13 labeling?

14 "ANSWER: Yes, I do recall it.

15 "QUESTION: Do you recall who made the
16 request?

17 "ANSWER: No, I don't. I can't point to a
18 specific individual.

19 "QUESTION: Do you know why Schering asked
20 for the labeling information?

21 "ANSWER: Oh, yeah. We had asked for it,
22 because we wanted to see what they were going
23 to consider providing to the FDA as the
24 labeling. Because the labeling, in our
25 industry, describes in effect what you can

1 state or make claims about your product.

2 "The Food and Drug Administration regulates
3 the promotion of prescription drugs and the
4 communication claims that you make about a
5 product have to be reflected in the labeling
6 program.

7 "QUESTION: Would that be communications
8 with physicians or patients about the product?

9 "ANSWER: Yes, in your promotional claims
10 that you make about your products to your
11 customer, specifically physicians or, in some
12 cases, patients.

13 "QUESTION: Do you know whether anyone at
14 Schering examined this labeling information
15 after it came in from Kos?

16 "ANSWER: Well, I recall myself, you know,
17 reading the labeling."

18 MR. GINSBURG: Page 121, line 12:

19 "MS. BOKAT: Would the court reporter
20 please mark as Driscoll Exhibit 46 a document
21 bearing the Bates number SP 002723 through
22 2727.

23 "QUESTION: Have you seen Driscoll Exhibit
24 36 previously?

25 "ANSWER: I actually -- I do recall

1 getting copied on this document.

2 "QUESTION: Was this the first proposal
3 from Schering to Kos or the first written
4 proposal?

5 "ANSWER: That I don't recall.

6 "QUESTION: In this proposal, is there any
7 offer of payment of up-front money from
8 Schering to Kos?

9 "ANSWER: No, I don't see one.

10 "QUESTION: Do you have any definite
11 recollection of Schering making proposals to
12 Kos after the one that is Driscoll Exhibit 36?

13 "ANSWER: No, I don't. I recall, though,
14 that it was around this time frame where I was
15 putting an end to all this. I don't have
16 specific dates, but my recollection is that
17 I'm not aware of any other written proposals
18 that were provided in draft form to Kos."

19 MR. GINSBURG: That's all, Your Honor, we have
20 from Mr. Driscoll's deposition. Thank you.

21 JUDGE CHAPPELL: Anything from Schering?

22 MS. BIERI: We do have some counters, Your
23 Honor.

24 MS. BIERI: Starting at page 73, line 5:

25 "QUESTION: Would you have" -- and this is

1 complaint counsel questioning the witness.

2 "QUESTION: Would you have needed more
3 information than the general description at
4 the meeting in Minneapolis in order to perform
5 an evaluation of the compound?

6 "ANSWER: We needed a little bit more, but
7 we had a general sense of the opportunity of
8 an effective sustained release niacin product
9 that brought clinical benefits to the market.
10 We had a general sense of what the value might
11 be, because we had been involved in valuating
12 that market for some time.

13 "QUESTION: Did you need more information
14 from Upsher-Smith in order to complete the
15 evaluation of extended release niacin?

16 "ANSWER: It was more just confirmatory.
17 No, we didn't need much more information. We
18 had sufficient information about what a
19 beneficial sustained release niacin would
20 bring to the market. I understood generally
21 what the value would be."

22 MS. BIERI: Going to page 76, line 4:

23 "QUESTION: Did anyone from Upsher-Smith
24 mention a cross license agreement between
25 companies and Upsher-Smith relating to patents

1 on extended release niacins?

2 "ANSWER: Cross license is a broad term.
3 I'd answer that by saying, as I answered
4 earlier, he described for us their patent
5 position on niacin for the sustained release
6 niacin. That Kos was paying them a royalty or
7 would have to pay them a royalty. I don't
8 think that -- I don't think Kos' product had
9 come to the market yet. I think it came later
10 that year, if I remember, '97. So, they would
11 have to pay a royalty.

12 "Now, the nature of that relationship he
13 did not describe; in other words, a cross
14 license or the like."

15 MS. BIERI: Going to page 96, line 3:

16 "QUESTION: After you had read the
17 labeling, did you communicate any thoughts to
18 anyone else at Schering about the labeling on
19 Niaspan?

20 "ANSWER: Yes, I did. I said it looks
21 interesting. This is -- again, we were,
22 myself specifically and my team, interested in
23 getting into the cholesterol lowering market.
24 It's a growing market. There were a lot of
25 marketplace resources for that and we were

1 interested in cholesterol lowering agents,
2 including niacin.

3 "Specifically we were interested in a
4 niacin sustained release product that would
5 bring clinical benefits to the market that
6 made it better than the existing niacin
7 products, the immediate release products.

8 "So, we had a general interest in reading
9 the labeling which, of course, was Kos'
10 labeling. Their description looked
11 interesting. I, of course, said to my team,
12 you know, we have to -- let's get information
13 that verifies this.

14 "QUESTION: That verifies the labeling?

15 "ANSWER: Well, yes, when a company
16 prepares the labeling, it's the company's view
17 of the data, but then, of course, it's filed
18 with the Food and Drug Administration. But
19 the Food and Drug Administration is the final
20 arbitrator, really, of what the labeling will
21 say.

22 "So, when we receive the labeling from a
23 company, in this case when we received it, in
24 this case I recall this, that it's nice, it's
25 interesting, now let's see the clinical trial

1 results that serve as the basis for why they
2 believe this will be the label.

3 "QUESTION: Did Kos provide their clinical
4 trial results on Niaspan to Schering?

5 "ANSWER: My recollection is they just
6 were not forthcoming with sufficient
7 information. And that really was one of the
8 basis for ultimately why I want -- one of the
9 reasons why I stopped the discussions with
10 them. They just weren't forthcoming with the
11 information, with the information that we were
12 requesting, including why they felt that they
13 were going to be able to get this labeling
14 when the product was approved."

15 MS. BIERI: Going to page 98, line 7:

16 "QUESTION: Did they give you any
17 information on their clinical trial results?

18 "ANSWER: They told us what their view of
19 the results were. In essence, the results,
20 clinical trial results in general, their view
21 of them, which was reflected in this labeling.
22 My recollection is they did not provide any
23 information to us to verify that that was the
24 case.

25 "QUESTION: What information would you

1 have needed from Kos to be sufficient to
2 verify these labeling claims?

3 "ANSWER: Well, every situation is
4 different. Different products, different
5 opportunities are all different, so that can
6 vary. But in this case something as simple as
7 a summary table of the results versus placebo,
8 for example. I don't recall whether these
9 were placebo controlled trials. But even
10 something as simple as summary tables, the
11 number of patients and discontinuation rates,
12 for example.

13 "Just some general information from the
14 clinical trial results would have been helpful
15 beyond what was described in the label."

16 MS. BIERI: Going to page 135, line 2:

17 "QUESTION: Did Mr. Zahn accept your
18 recommendation to end the discussions with
19 Kos?

20 "ANSWER: I believe he did, because we
21 did.

22 "QUESTION: Do you recall when the
23 discussions with Kos were ended?

24 "ANSWER: I do recall it was right about
25 this time.

1 "QUESTION: So, it was shortly after your
2 memo to Mr. Zahn; is that right?

3 "ANSWER: I honestly don't know the
4 specific date. I do recall that even prior to
5 writing this I told my people that was going
6 to be it. We weren't going to discuss it
7 further with them. I didn't see the
8 opportunity as being sufficient for all the
9 reasons I articulated earlier. They weren't
10 forthcoming with information.

11 "In addition to that, an important factor
12 was their manner in which their people were
13 treating mine. Their opportunity that they
14 were -- they were demanding was co-promotion
15 opportunity, meaning they would promote it
16 along with us. And in any co-promotion
17 situation, I have had a lot of experience
18 here, you have to have a good feeling for your
19 potential partner, and trust. And the manner
20 in which they were treating my people was
21 unacceptable to me. So that was an additional
22 reason why I told my people to stop."

23 MS. BIERI: That's all we have, Your Honor.

24 JUDGE CHAPPELL: Thank you.

25 MR. CARNEY: Your Honor, Upsher's designations

1 are within those that were counter-designated by
2 Schering, so we have nothing to add.

3 JUDGE CHAPPELL: Okay, next, Ms. Bokat?

4 MS. BOKAT: The next readings will be from John
5 Hoffman's investigational hearing transcript. That
6 investigational hearing was conducted July 25th, 2000.
7 John Hoffman is a lawyer employed by Schering-Plough in
8 their legal department, I believe he's antitrust
9 counsel.

10 MR. GINSBURG: Page 75, line 21:

11 "QUESTION: Was there any discussion of
12 including a provision in the agreement to
13 cover the possibility that Niacor wouldn't be
14 approved?

15 "ANSWER: No.

16 "QUESTION: Was there a reason for the
17 negotiations of the license and the patent
18 settlement occurring at the same time?

19 "ANSWER: I believe I described Mr.
20 Troup's statements to that, that it was all
21 well and good for us to -- for Schering to
22 propose a license to take effect in the
23 future. But that they needed to work out some
24 way to get some cash for their own needs, and
25 that maybe they would license something to us.

1 "QUESTION: Did you have a sense of
2 whether Mr. Troup would have been willing to
3 enter into the license of his products to
4 Schering absent a settlement of the patent
5 litigation?

6 "ANSWER: I believe so, yes, I believe so.

7 "QUESTION: So as long as Mr. Troup got
8 revenues from Schering for something, was he
9 willing to settle the patent litigation?

10 "ANSWER: He didn't say that. He said it
11 was necessary for his company if we were going
12 to settle it with the type of arrangement we
13 were discussing -- with the royalty-free
14 license in the future -- to get some revenue
15 now. And that turned out to be licensing."

16 MR. GINSBURG: That's all, Your Honor, we have
17 from Mr. Hoffman's investigational hearing. Thank you.

18 MS. BIERI: May we just have one minute, Your
19 Honor, to confer?

20 JUDGE CHAPPELL: Yes.

21 (Pause in the proceedings.)

22 MS. BIERI: Okay, Your Honor, we just have a
23 few.

24 JUDGE CHAPPELL: Okay.

25 MS. BIERI: This is complaint counsel

1 questioning at the beginning, page 74, line 25:

2 "QUESTION: Did he make any" -- and I'm
3 sorry, the "he" there, just to put it in
4 context, is Mr. Troup.

5 "QUESTION: Did he make any
6 representations about the costs Upsher-Smith
7 had sustained in developing those products?

8 "ANSWER: No. He said that it had been a
9 very expensive process. But he did not, as I
10 recall, mention any particular figures.

11 "I recall him discussing a substantial part
12 of their R&D budget had gone into development.

13 "QUESTION: Of all the licensed products,
14 or any one in particular?

15 "ANSWER: I particularly recall with
16 respect to a sustained-release niacin
17 product."

18 MS. BIERI: Going to page 76, line 24:

19 "QUESTION: Did Mr. Troup care whether the
20 license and the patent settlement were in one
21 agreement document?

22 "ANSWER: Not that I know of.

23 "QUESTION: Was there any particular
24 reason for covering the patent settlement and
25 the license in one document?

1 "ANSWER: Not that I know of, other than
2 time.

3 "QUESTION: Now, time gets me to another
4 question. You mentioned that there was a very
5 long night after the trip to Minneapolis. Was
6 there some urgency in finalizing the
7 agreement?

8 "ANSWER: We just wanted to get this
9 wrapped up. As I recall, trial was scheduled
10 to start in the patent case. If we were going
11 to have the judge put that on hold or stop the
12 trial, if we wanted to do that, we didn't want
13 to annoy a judge by starting a trial and then
14 stopping it. So we wanted to get that wrapped
15 up."

16 MS. BIERI: That's all, Your Honor.

17 JUDGE CHAPPELL: Upsher?

18 MR. CARNEY: Nothing to add, Your Honor, for
19 Upsher.

20 JUDGE CHAPPELL: Next?

21 MS. BOKAT: The next readings will be from the
22 investigational hearing transcript of Raman Kapur. The
23 hearing was conducted July 21st, 2000. Mr. Kapur is a
24 Schering official. He's head of Schering's Warrick
25 subsidiary, the generic subsidiary.

1 JUDGE CHAPPELL: Thank you.

2 MR. GINSBURG: Page 105, line 17:

3 "QUESTION: We talked earlier in the day
4 about the packet of information that
5 Upsher-Smith provided to Schering on Niacor.
6 Did Upsher-Smith provide any other written
7 documents in the course of the negotiations?

8 "ANSWER: That's what I said earlier, that
9 I really don't recall at what point the
10 protocols for clinical trials or the costs of
11 the trials, but I'm not aware of, you know, I
12 was not involved in any other discussions they
13 may have had. I don't know what else -- so
14 far, based on my direct knowledge, there were
15 these documents that came across my desk.

16 "QUESTION: Do you recall anything else
17 coming across your desk?

18 "ANSWER: I don't recall -- on the -- with
19 the Niacor product? You said?

20 "QUESTION: In the course of the
21 negotiations, whether it was about Niacor or
22 pentoxifylline or any of the other products
23 you were discussing with Upsher-Smith.

24 "ANSWER: No. I recall this coming
25 through the document that you had provided to

1 me here.

2 "QUESTION: Which is Exhibit Number 8?

3 "ANSWER: Yeah, Exhibit Number 8. I
4 remember some protocols coming through, but I
5 don't recall if there was anything else. That
6 doesn't mean there couldn't have been
7 something else, but I don't recall it.

8 "QUESTION: Other than the work that
9 global marketing and business development did
10 on Niacor, was there any other due diligence
11 done by Schering or Warrick on the Niacor
12 product?

13 "ANSWER: Not by Warrick, and I couldn't
14 answer what Schering did, because that's --
15 global marketing would know that or Schering
16 would know that. Warrick did not do anything,
17 due diligence, on the Niacor product."

18 MR. GINSBURG: Page 138, line 3:

19 "ANSWER: I have only a very general
20 recollection of the meeting with the
21 magistrate where ESI Lederle had felt they
22 were entitled to certain sums of money and
23 John Hoffman told the magistrate that we could
24 not do that. We could not pay them any money,
25 but we will -- and Marty reaffirmed that and

1 told them that, you know, he could discuss
2 with them if there were other opportunities
3 where -- which were to their benefit and
4 Schering's benefit, but he couldn't make
5 payment to them. And that was the sum and
6 substance of it. The details, I don't recall.

7 "QUESTION: Did ESI say who they thought
8 they were entitled to money from?

9 "ANSWER: From Key."

10 MR. GINSBURG: Page 139, line 11:

11 "QUESTION: Was ESI offering to stay off
12 the market with their generic version of K-Dur
13 20 if the case settled and they were paid?

14 "ANSWER: For a certain period of time if
15 the case settled and they were paid so they
16 could make up their revenue stream. That was
17 their --

18 "QUESTION: At this first meeting, was
19 there discussion of how long ESI would be
20 willing to stay off the market?

21 "ANSWER: I don't recall whether it was at
22 the first meeting or subsequent meetings or
23 when it took place exactly. But, I don't
24 recall.

25 "QUESTION: At some point did ESI indicate

1 how long they were willing to keep their
2 generic of K-Dur off the market?

3 "ANSWER: In the course of the
4 negotiations, at some point it was 2004, I
5 believe."

6 MR. GINSBURG: Page 140, line 23:

7 "QUESTION: Was there any discussion of
8 the kinds of opportunities that might benefit
9 both Schering and ESI?

10 "ANSWER: I believe Marty did have some
11 discussion with ESI about whether there was a
12 possibility of ESI comarketing Schering's
13 products or providing -- whether Schering
14 could -- whether they could help bill Schering
15 business where both parties would benefit from
16 that business, and then they could look at
17 that as a separate activity. But, you know, I
18 don't recall the details of that because I was
19 not that concerned about that part of this
20 discussion."

21 MR. GINSBURG: That's all, Your Honor, we have
22 from Mr. Kapur's investigational hearing.

23 JUDGE CHAPPELL: Thank you. Anything from
24 Schering?

25 MS. BIERI: We have some brief

1 counter-designations.

2 JUDGE CHAPPELL: You may proceed.

3 MS. BIERI: Your Honor, I'll warn you, there's
4 going to be a little bit of repetition here for
5 context, some of the designations that they read will
6 be interspersed with what we're reading around it.

7 JUDGE CHAPPELL: That's fine.

8 MS. BIERI: Thank you. Starting at page 135,
9 line 16, complaint counsel questioning:

10 "QUESTION: When did you first become
11 involved in the negotiations with ESI?

12 "ANSWER: In the context of this
13 present -- of this settlement or have I had
14 any contact? I just want to be sure of that.

15 "QUESTION: In the context of this
16 settlement.

17 "ANSWER: All right, the first time, the
18 first active involvement was a visit to the
19 magistrate in Philadelphia.

20 "QUESTION: Do you recall when that visit
21 to the magistrate occurred?

22 "ANSWER: I don't recall the exact date.
23 It was somewhere in late -- somewhere late in
24 1997.

25 "QUESTION: Who attended the visit to the

1 magistrate?

2 "ANSWER: Second half of '97 I would say.

3 Who attended that?

4 "QUESTION: Yes.

5 "ANSWER: I was present at two meetings
6 with the magistrate. The first meeting -- I
7 won't be able to tell you, my recollection is
8 not good, as to all the participants, but the
9 magistrate was there, Michael Dey, who is the
10 head of ESI, was there, his attorney was
11 there, Marty Driscoll, John Hoffman, myself.
12 I don't know if there were other people, but
13 those are the people I recall."

14 MS. BIERI: Going to page 137, line 24,
15 complaint counsel questioning:

16 "QUESTION: What was discussed that
17 meeting with the magistrate?

18 "ANSWER: The first one or the second?

19 "QUESTION: Well, let's start with the
20 first one.

21 "ANSWER: I have only a very general
22 recollection of the meeting with the
23 magistrate where ESI Lederle had felt they
24 were entitled to certain sums of money, and
25 John Hoffman told the magistrate that we could

1 not do that. We could not pay them any money,
2 but we will. And Marty reaffirmed that and
3 told them that, you know, he could discuss
4 with them if there were other opportunities
5 where -- which were to their benefit and
6 Schering's benefit, but he couldn't make
7 payment to them, and that was the sum and
8 substance of it. The details, I don't recall.

9 "QUESTION: Did ESI say they thought they
10 were entitled to money from --

11 "ANSWER: From Key?

12 "QUESTION: Did they say why they thought
13 they were entitled to money from Key?

14 "ANSWER: As part of a settlement. The
15 magistrate was pushing. The magistrate
16 supposedly had said he had direction from the
17 judge to try and settle this, and he was going
18 to push to settle it and, you know, Marty
19 wanted to -- told the magistrate that, look,
20 we don't want to settle this. We have a
21 strong lawsuit. We'll go on with the case. I
22 guess ESI was willing to settle in exchange
23 for some money that they would stay off the
24 market for a period of time, and Marty was
25 saying he didn't want to do that. He didn't

1 want to -- he didn't want to settle. He
2 wanted to go on with the trial."

3 MS. BIERI: That's all, Your Honor.

4 JUDGE CHAPPELL: Thank you. Upsher?

5 MR. CARNEY: Nothing to add for Upsher, Your
6 Honor.

7 JUDGE CHAPPELL: Ms. Bokat, before we continue,
8 what is your estimate of time for your direct exam of
9 Larry Rosenthal?

10 MS. BOKAT: My best estimate, and I'm
11 notoriously bad at this, is approximately an hour and a
12 quarter, Your Honor.

13 JUDGE CHAPPELL: And do you have another
14 witness you're going to call tomorrow also?

15 MS. BOKAT: No.

16 JUDGE CHAPPELL: What's your plan for what
17 we're going to do the rest of tomorrow?

18 MS. BOKAT: Well, we have readings --
19 additional readings that we can use to fill tomorrow,
20 but Dr. Levy couldn't come back tomorrow afternoon,
21 which is why --

22 JUDGE CHAPPELL: I understand that. Is Larry
23 Rosenthal your last live witness?

24 MS. BOKAT: No, we have one more live witness,
25 another of our experts, Joel Hoffman.

1 JUDGE CHAPPELL: Right. Well, I know -- I read
2 your trial brief, but I didn't know if you had changed
3 your trial plan since we began. That's why I'm asking.

4 MS. BOKAT: Right. No, Mr. Hoffman would be
5 our last witness.

6 JUDGE CHAPPELL: Is he available tomorrow?

7 MS. BOKAT: I don't know. We hadn't explored
8 that, because I wasn't trying to chop up the interval
9 between our direct of Dr. Levy and respondents'
10 opportunity for cross examination.

11 JUDGE CHAPPELL: Okay. So, we will finish with
12 Larry Rosenthal tomorrow, and then we will finish with
13 your deposition excerpt readings and see where we stand
14 at that time.

15 We're going to have to have a break after Mr.
16 Rosenthal's direct, because I'm going to take a break,
17 review the transcript from his prior deposition, and
18 then I'm going to give respondents time to review that
19 before they cross examine the witness, just for
20 planning purposes.

21 Okay, that's what I need to know. Thank you.
22 You may proceed.

23 MR. GINSBURG: Thank you.

24 MS. BOKAT: So, the next readings would be
25 again from Mr. Kapur, this time from his deposition

1 transcript. That deposition was taken October 18th,
2 2001.

3 JUDGE CHAPPELL: Go ahead.

4 MR. GINSBURG: Thank you, Your Honor.

5 Page 82, line 23:

6 "QUESTION: During the discussions between
7 yourself and Mr. Troup -- now, this is
8 spanning from May 28th to June 17th -- did you
9 or someone else at Schering inquire about the
10 patent status of Niacor-SR?

11 "MS. SHORES: Objection, compound, also
12 speculation.

13 "ANSWER: No, if your question is did I do
14 anything about the patent status, was I
15 present at -- where the patent was
16 investigated, I was not present in the
17 discussion of the patents.

18 "QUESTION: Did you ask anyone at
19 Schering-Plough to look into the patent status
20 of Niacor-SR?

21 "MS. SHORES: I'll object to that on the
22 ground that it potentially calls for a
23 privileged communication. If you want to ask
24 him whether he asked anybody other than a
25 lawyer?

1 "MS. BOKAT: I'd like to just ask him
2 generally first.

3 "MS. SHORES: Well, then, I'll instruct the
4 witness if you asked a lawyer about the patent
5 status, I wouldn't discuss that.

6 "ANSWER: I didn't ask anybody. My role
7 was as a negotiator. You know, this -- I
8 passed the package on to the business
9 development people and the global marketing
10 people whose business it was. It wasn't my
11 role to go into that, into the patents or into
12 the other areas of the product. I was there
13 as a negotiator. You put that question to
14 other people, maybe business development or
15 global marketing or those -- or other areas.

16 "QUESTION: Did you personally inquire of
17 Upsher-Smith about their communications with
18 the Food and Drug Administration concerning
19 Niacor-SR?

20 "ANSWER: Again, that was not my role.
21 You know, I did not do that. I passed the
22 package on to business development, the people
23 whose business this was. My role was only to
24 negotiate the deal, to help them negotiate and
25 get the best deal and to get products for

1 myself. That was my role. The rest of it was
2 theirs.

3 "QUESTION: Did you ask anyone at
4 Schering-Plough to inquire into communications
5 between Upsher-Smith and the Food and Drug
6 Administration concerning Niacor?

7 "ANSWER: Again, I did not. That was not
8 my role. That would have been -- whatever was
9 done in those arenas would have been -- should
10 be addressed to the business people whose
11 business this was.

12 "QUESTION: Do you know whether anyone at
13 Schering inquired into communications between
14 Upsher-Smith and the Food and Drug
15 Administration concerning Niacor?

16 "ANSWER: I don't know."

17 MR. GINSBURG: Page 98, line 22:

18 "QUESTION: Then did you as negotiator not
19 send the Upsher agreement to the controller,
20 the tax department, the law department and the
21 treasury department within Schering?

22 "ANSWER: I don't recall sending this
23 agreement to any of those units. I think you
24 would have to ask Jeff Wasserstein or others
25 what they did with it, but it was not my

1 bailiwick."

2 MR. GINSBURG: That's all, Your Honor, we have
3 for Mr. Kapur's deposition. Thanks.

4 JUDGE CHAPPELL: Upsher?

5 MS. BIERI: Schering has no counters for this.

6 JUDGE CHAPPELL: Schering has no counters.

7 What about Upsher?

8 MR. CARNEY: Nothing from Upsher, Your Honor.

9 JUDGE CHAPPELL: Next?

10 MS. BOKAT: The next is from the
11 investigational hearing transcript of Jeffrey
12 Wasserstein. That hearing was conducted September
13 14th, 2000. Mr. Wasserstein is an official of
14 Schering-Plough. Last time I tried to read his title,
15 I misspoke and Ms. Shores corrected me. Would she be
16 willing to help me out at this point?

17 MS. SHORES: Yes, Mr. Wasserstein is
18 currently -- now I'm going to mess this up -- he -- at
19 the time of his deposition, he was -- let me get this
20 right, too.

21 Hold on one second, Your Honor.

22 JUDGE CHAPPELL: Don't worry if you get it
23 wrong. It's just a matter of public record, Ms.
24 Shores. I'd like to know what his job is now and what
25 it was at the time of this testimony, if it's

1 different.

2 MS. SHORES: Just one second, Your Honor.

3 MS. BOKAT: It gets complicated, Your Honor,
4 because I think at the time of the agreement, he was in
5 corporate business development, by the time we took the
6 investigational hearing, he was working for a Schering
7 unit in Canada.

8 MS. SHORES: That's correct, Your Honor. He
9 was the head of Schering Canada at the time of the
10 investigational hearing. He has since moved on to
11 another position, which I believe is the staff vice
12 president and head of the GMP manufacturing processes
13 at Schering.

14 JUDGE CHAPPELL: Thank you.

15 MR. GINSBURG: Page 98, line 24:

16 "MR. EISENSTAT: I'd like to have marked as
17 the next exhibit in order Wasserstein 4, a
18 ten-page document bearing the numbers SP
19 1200244 through SP 1200253.

20 "QUESTION: Mr. Wasserstein, you've been
21 handed what's been marked as Exhibit 4. Let
22 me just move 3 out of the way so you -- I'll
23 leave them in the middle of the table if you
24 need to refer to them, but otherwise, I
25 thought we'd just keep the table a little more

1 orderly. I'd like to ask you to look over
2 Exhibit 4 and ask you if you recognize what
3 the document is.

4 "ANSWER: It looks like the board of
5 directors presentation on our transactions
6 with Upsher-Smith."

7 MR. GINSBURG: Page 108, line 1:

8 "QUESTION: Okay, let's keep going down
9 the page where it says -- we're still on SP
10 120046. There's a heading in the middle of
11 the page, Niacor-SR, and under that it says,
12 'Niacor-SR is a patented sustained release
13 niacin product. Upsher-Smith will be filing
14 an NDA for the product in the U.S. by year
15 end.' Do you see that line?

16 "ANSWER: Yes.

17 "QUESTION: NDA, is that a new drug
18 application?

19 "ANSWER: Yes."

20 MR. GINSBURG: Page 108, line 20:

21 "QUESTION: If we skip a line, the next --
22 skip a sentence, there's a sentence that says,
23 'It offers a 100 million plus in annual sales
24 opportunity for Schering-Plough.' Do you see
25 that sentence?

1 "ANSWER: Yes.

2 "QUESTION: Where did you get the 100
3 million plus in annual sales number?

4 "ANSWER: That was based on the final
5 analysis that had been provided to us by
6 global marketing.

7 "QUESTION: So, you are relying on global
8 marketing for that number?

9 "ANSWER: Yes, uh-huh.

10 "QUESTION: Okay. The final sentence of
11 that paragraph says, 'A key to Niacor-SR
12 achieving these sales are, labeling for
13 lowering cholesterol both as monotherapy and
14 in combination with statins, reimbursement in
15 the core countries and a good safety profile.'
16 Do you see that sentence?

17 "ANSWER: Yes.

18 "QUESTION: What did you mean where you
19 say, 'A key to Niacor achieving these sales
20 are labeling for lowering cholesterol both as
21 monotherapy and in combination with statins'?

22 "ANSWER: That means labeling for the
23 product, that it could be used by itself.
24 That's what the monotherapy means. For
25 lowering cholesterol and in combination,

1 meaning labeling that says 'and in combination
2 with the class of drugs of statins could lower
3 cholesterol.'

4 MR. GINSBURG: Page 111, line 21:

5 "QUESTION: Okay, there's a heading right
6 underneath that paragraph that says,
7 'Niacor-SR opportunity,' and the first
8 sentence says, 'Based on data generated by
9 Upsher-Smith, Niacor-SR appears to have less
10 adverse effects, flushing, itching,
11 hepatotoxicity, than other forms of niacin.'
12 Do you know what you based that sentence on?

13 "ANSWER: I don't recall specifically, but
14 presumably as it says, based on data that had
15 been provided to us by Upsher-Smith, which to
16 the extent that they were the ones doing the
17 clinical trials and we hadn't done any
18 independent clinical trials, which is not
19 unusual, it would be relying on that data.

20 "QUESTION: Okay. Would you have gone
21 through that data yourself or would you be
22 relying on global marketing's review of that
23 data?

24 "ANSWER: I would be relying on someone
25 else's review and presumably global marketing

1 would have either -- would have been either
2 doing the review themselves or relying on
3 somebody in research or a business unit to
4 provide them with that data.

5 "QUESTION: But you didn't do the
6 review --

7 "ANSWER: I did not do it, no.

8 "QUESTION: And similarly, in the next
9 sentence, they give some actual numbers. 'in
10 addition, in clinical trials, it has been
11 shown by Upsher-Smith that Niacor-SR can
12 reduce LDL-C by 20 percent, raise HDL by 16
13 percent and reduce TGs by 16 percent.' Were
14 you relying on global marketing for that
15 information?

16 "ANSWER: Yes.

17 "QUESTION: The last sentence then says,
18 'As outlined in Table 1, Niacor-SR is expected
19 to be launched in early 1999 with third-year
20 sales of \$114 million.' Would that also be
21 coming from global marketing?

22 "ANSWER: Yes.

23 "QUESTION: There is then a heading that
24 says Payment Terms, and the first paragraph
25 says, 'In the course of our discussions with

1 Upsher-Smith, they indicated that a
2 prerequisite of any deal would be to provide
3 them with a guaranteed income stream for the
4 next 24 months to make up for the income that
5 they had projected to earn from the sales of
6 Klor Con had they been successful in their
7 suit.' Is that the discussion you vaguely
8 recalled earlier this morning that Mr. Troup
9 told you?

10 "ANSWER: Yes.

11 "QUESTION: Let's turn to the page bearing
12 the number SP 1200251 labeled Table 1,
13 Niacor-SR Worldwide Sales, Except the U.S.,
14 Canada and Mexico. Do you have that page in
15 front of you?

16 "ANSWER: Yes, I do.

17 "QUESTION: Did you just take this page
18 from the work that global marketing did?

19 "ANSWER: Yes.

20 "QUESTION: So, you are just replicating
21 the work they did. You didn't actually do
22 this work.

23 "ANSWER: That's correct.

24 "QUESTION: These assumptions and
25 rationale, are those global marketing's

1 assumptions and rationale?

2 "ANSWER: Yes.

3 "QUESTION: Let's turn to the next page,
4 the page labeled SP 1200252, labeled Niacor-SR
5 Earnings Impact. Do you have that page in
6 front of you?

7 "ANSWER: Yes, I do.

8 "QUESTION: Now, when you say earnings
9 impact here, this is not actual earnings that
10 the company actually made. This is a
11 projection of earnings. Is that correct?

12 "ANSWER: This is the projection of the
13 impact of the transaction on Schering-Plough
14 Corporation as a whole.

15 "QUESTION: Okay, but it's a projection.

16 "ANSWER: Yes.

17 "QUESTION: This isn't actual dollars you
18 earned.

19 "ANSWER: No, it's not."

20 MR. GINSBURG: Page 115, line 4:

21 "QUESTION: But your understanding is that
22 Schering never marketed Niacor-SR.

23 "ANSWER: That's what I think, yes."

24 MR. GINSBURG: Page 124, line 17:

25 "QUESTION: Do you know anything about the

1 reasons why Upsher-Smith never finished the
2 registration of the product and why Schering
3 or why Schering-Plough didn't sell the
4 product?

5 "ANSWER: No.

6 "QUESTION: You weren't involved in that
7 at all?

8 "ANSWER: No. My participation on this
9 ended with the board of directors document
10 that we looked at before.

11 "QUESTION: You did no more work on the
12 product?

13 "ANSWER: None."

14 MR. GINSBURG: That's all, Your Honor, we have
15 from Mr. Wasserstein's investigational hearing. Thank
16 you.

17 JUDGE CHAPPELL: Thank you. Schering?

18 MS. BIERI: Schering has no counters, Your
19 Honor.

20 MR. CARNEY: No counter-designations for
21 Upsher, Your Honor.

22 JUDGE CHAPPELL: According to the clock on the
23 wall, it's about 5:25, and rather than start another
24 reading, this should be a pretty good breaking point, I
25 think, and it would help us keep things more coherent

1 in the record.

2 So, we'll recess until 9:30 tomorrow morning.

3 (Whereupon, at 5:25 p.m., the hearing was
4 adjourned.)

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1 C E R T I F I C A T I O N O F R E P O R T E R

2 DOCKET/FILE NUMBER: 9297

3 CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

4 DATE: JANUARY 31, 2002

5

6 I HEREBY CERTIFY that the transcript contained
7 herein is a full and accurate transcript of the notes
8 taken by me at the hearing on the above cause before
9 the FEDERAL TRADE COMMISSION to the best of my
10 knowledge and belief.

11

12 DATED: 2/1/02

13

14

15

16 SUSANNE BERGLING, RMR

17

18 C E R T I F I C A T I O N O F P R O O F R E A D E R

19

20 I HEREBY CERTIFY that I proofread the
21 transcript for accuracy in spelling, hyphenation,
22 punctuation and format.

23

24

25 DIANE QUADE

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